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1 P R O C E E D I N G S

2 MR. HUBBARD: Good morning. I'm Bill Hubbard
3 from the Commissioner's Office at FDA. We're running a
4 little late because Joe Levitt, who is going to chair this,
5 is caught in traffic. He should be here momentarily. We
6 might be able to do some initial housekeeping things,
7 however, that we were going to do anyway, to prepare for
8 him.

9 So, with that, let me first introduce Margaret
10 Porter, our General Counsel, and Beth Yetley, the head of
11 our dietary supplements office--

12 DR. YETLEY: Office of Special Nutritionals.

13 MR. HUBBARD: Excuse me.

14 [Laughter.]

15 MR. HUBBARD: And Dr. Debra Bowen, from our Center
16 of Drug Evaluation and Research.

17 Perhaps the first thing to do is to give you a
18 brief run-through of what we're going to do today and how
19 we're going to organize the meeting.

20 Beth, could you do that?

21 DR. YETLEY: Joe Levitt does have some opening
22 remarks, so when he gets here we'll let him go ahead and do
23 that, although I think that would probably be between Panels I
24 and II.

25 What we have done is try to organize this by

1 panels that appeared to have somewhat common interests. We
2 have six panels scheduled, and then at the end of the day we
3 will have some concluding remarks.

4 The first panel is primarily trade associations,
5 then we have nutrition professionals. A third panel will be
6 consumer groups; fourth panel nutraceuticals. A fifth panel
7 is consumer groups, and the six panel is, again, industry
8 and industry representatives.

9 We will ask the entire panel to come up as a
10 group. We will ask each member of that panel to give their
11 remarks. We've asked them to keep this to five minutes or
12 less. And then once the entire group has given their
13 remarks, we will try to have a dialogue between those of us
14 on the FDA side, and the members of the panel. This is as
15 much information gathering, from our prospective, as we can
16 make it. And so we wanted to have as much dialogue as we
17 could.

18 The first panel, we have APHA, Lucinda Maine--I'll
19 have you start up and wind yourself around the table--CHPA,
20 Bill Soller; NFPA, Regina Hildwine; CRN, Annette Dickinson;
21 RDIA, Maureen Mackey, and we also asked NNFA, Michael Ford
22 to join this panel.

23 If they could come forward?

24 [Pause.]

25 MR. HUBBARD: Could I speak to Lynn Larsen to a

1 minute?

2 DR. YETLEY: Lynn, we're looking for the timer. I
3 understand we have a timer so people stay on schedule.

4 Okay, Ellen, down here, is going to--what?--hold
5 up cards. Yellow means caution, I presume, and red means'
6 you're time is up.

7 Okay. We have a very full schedule, so we are
8 going to be a little bit hard-nosed about sticking with the
9 schedule.

10 APHA--Lucinda Maine.

11 MR. HUBBARD: Lucinda, let me interrupt you. Joe
12 Devitt is walking in now. Perhaps it would be best to go
13 back to the original schedule.

14 Joe, you need to come around. Sorry about that.

15 [Laughter.]

16 MR. LEVITT: Good morning, everyone. Let's see if
17 this microphone is working. It sounds like it is.

18 I apologize to everyone, including the panelists
19 up here, for my late arrival. You know what they say: the
20 best laid plans. If you need to get here quickly, you will
21 find the traffic jam in Washington--at least is what I've
22 found.

23 At least I can tell you that it is cooler in here
24 than it is out there. As the day goes on, we hope the air
25 conditioning holds. If it does not, I would encourage

1 people to freely--whether you're up here on the panel or
2 not, to take off your jackets, or whatever is needed, so
3 that we have a comfortable day.

4 What I would like to do--if we can get the slide
5 projector going--is to set the stage for the speakers that
6 we have today. And Lynn is telling me--I'm just going to
7 use the mike here, because I don't think I could get there.
8 The only question is will it at all affect how I move the
9 slight. Pardon me. I just couldn't quite figure out how to
10 get from here to there.

11 [Pause.]

12 We'll start off again with a welcome. We'll
13 welcome the members of the FDA panel; the folks from the
14 industry; consumers; health professionals; and everybody
15 that is here in the audience.

16 I hope this will be a useful day. We would like
17 to try and do three things. I've got to remember my rules
18 here.

19 Number one is--most importantly--we want to share
20 views. We at the FDA want to hear what all the stakeholders
21 have to say about dietary supplement strategy.

22 Number two, really, is a goal. Sometime in this
23 area it feels like a dream. But to the extent that we can
24 build consensus, obviously that is good. In order to do
25 that--and I said this at an earlier meeting--I really ask

1 all the speakers--I make you this deal. I'll listen to each
2 of you, as will my colleagues, if you'll listen to each
3 other. Because we will hear, I have no doubt, differing
4 points of view on this subject. And it's important that
5 everybody understand the different points of view if we have
6 a chance and a hope of building consensus. And even without
7 consensus, we need to prioritize the work we have to do.
8 There's a lot of important work to be done in this area. We
9 recognize and are becoming more, if you will, humbled by the
10 scope and depth and breadth of what we need to do. And so
11 one absolute goal I have out of this process is to
12 prioritize.

13 Now, in terms of background, this meeting really
14 has its origins in a meeting in this room just about year
15 ago, when we had a general stakeholders meeting of CFSAN.
16 We had a number of oral and written presentations, and we
17 really focused on the central question: where do we do the
18 most good for consumers?

19 That developed into the CFSAN program priorities
20 document for 1999--what I finally referred to as the "Yellow
21 Book." And one of the main features under dietary
22 supplements there was to say: we need to take a step back.
23 We need to recognize that we've had four years of experience
24 since DSHEA, but we need to take a step back and really
25 develop an overall strategy for how we're going to implement

1 this law. And, as you see, there are a long list of things
2 that are listed, and all those are relevant.

3 Now, Dr. Henney, when she testified before
4 Congress earlier this spring, I think made a number of key
5 statements that will help frame our discussions for today.

6 Number one, she said FDA is aware that Americans
7 place great faith in dietary supplements to help maintain
8 and improve their health, and that the scientific evidence
9 documenting the benefits of a number of supplements is
10 increasing. So there's value here. We need to recognize
11 that.

12 But, number two, the challenge to FDA is to strike
13 the right balance between preserving consumers' access to
14 both products and information, while assuring the safety and
15 proper labeling of all these products. So we have access on
16 the one hand; we have safety, proper labeling on the other
17 hand, and we need to achieve both.

18 Now, we've also made a considerable set of
19 progress to date. Attached to Dr. Henney's testimony was a
20 list of the Federal Register documents that have been
21 published since DSHEA on dietary supplements. We took a
22 short little poll in FDA. Nobody outside of the Office of
23 Special Nutritionals thought there were more than ten. But
24 as we counted them all up, indeed there were 25 Federal
25 Register documents already, which shows there has been a lot

1 of work but, also, we realize a lot more to be done.

2 In addition to the Federal Register, you see we
3 receive large numbers of 30-day notifications, as well as a
4 number of scientific-based new dietary supplement ingredient
5 notifications that we have dealt with.

6 Dr. Henney then continued, therefore, "It is
7 clear, with the benefit of hindsight, that we still have a
8 way to go, both in achieving full compliance with DSHEA, and
9 in developing a workable regulatory framework." I really
10 hope that today is the day that starts us vigorously along
11 that path.

12 Now, we also--this is part of a broader outreach
13 effort--again, I talked about the meeting a year ago. We
14 had a meeting in January dealing with international
15 scheduling. Dr. Henney had an agency-wide stakeholder
16 meeting in April. We held one here in the Center, on health
17 claims on dietary supplements--and I see some of the same
18 speakers on the first panel that I was able to hear then.
19 We have today's meeting on overall strategy, and we are
20 repeating this same meeting on the West Coast on July 20th.

21 Now, we put out a Federal Register notice, which
22 you all, no doubt, got, or you wouldn't be here today.
23 Again, reinforcing the statements I already read, FDA's
24 objective in developing this strategy is to ensure consumer
25 access to safe dietary supplements that are truthfully and

1 misleadingly labeled, following a process of openness,
2 flexibility, efficiency and commitment to public health.

3 We propose four criteria in setting priorities:
4 number one, consumer safety; number two, health-related
5 labeling; number three, efficiencies in the process; and
6 number four, closure on unresolved issues. And those
7 familiar with my general priority-setting process will see a
8 clear similarity there.

9 We posed seven questions in the Federal Register
10 notice, and I will run through those briefly, that we hope
11 people will be addressing.

12 Number one: in addition to ensuring consumer
13 access to safe dietary supplements that are truthfully and
14 not misleadingly labeled, are there other objectives that an
15 overall strategy should include?

16 Number two: are the criteria that I just went
17 over--are the criteria for prioritizing the tasks within the
18 supplement strategy appropriate? What specific tasks should
19 FDA undertake first?

20 Number three: what factors should FDA consider in
21 determining how best to implement the tasks; i.e., the use
22 of regulations, guidance, etcetera--what approach should we
23 take?

24 Number four: what specific tasks should be
25 included under the various dietary supplement program

1 elements in the CFSAN priorities document--and I went
2 through those earlier--claims, boundaries, CNPs, GMPs,
3 etcetera.

4 Number five: are there current safety labeling or
5 other marketplace issues that we should address quickly? We
6 sometimes talk about the difference between something that
7 is important and something that is urgent. And some things
8 are both, but some things are more urgent than others, and
9 some things are important over the long haul, but not
10 necessarily something that has to be done first, or right
11 away. So are there things that FDA should address quickly
12 through enforcement actions to ensure, for example, that
13 consumers have confidence that the products on the market
14 are safe and truthfully and not misleadingly labeled.

15 Number six: what type or area of research on
16 dietary supplements should FDA allocate its resources; so,
17 focusing on research.

18 And, finally, how we can leverage. Given FDA's
19 limited resources, what mechanisms are available or should
20 be developed to leverage FDA's resources to meet effectively
21 the objective of the strategy.

22 Now, I'll share with you our current thinking as
23 we've been talking and meeting as we've led up to this
24 meeting, too, and I would take those earlier long lists and
25 really put them under three broad headings.

1 Number one: what are the boundaries? If we're
2 going to have a set of rules for regulating dietary
3 supplements, I think the first step is, what is a dietary
4 supplement? What falls within those rules, and what falls
5 within other sets of rules; whether it's food additive,
6 drug, conventional food, or whatever.

7 Number two is safety, and I would put this in both
8 acute safety issues, such as adverse even reporting, as well
9 as longer term things that will help promote safety, like
10 GMPs.

11 And third is the whole area of labeling and
12 claims.

13 Now, meeting logistics--I think this has been gone
14 over, but just to reiterate briefly--we have a series of
15 panels. The first one is sitting up here already nicely.
16 We will ask each speaker in the panel to go over and give
17 their presentation. I would ask you not to follow my lead--
18 you've already been here before me. We do have to focus on
19 timeliness if we're going to allow everybody a chance to
20 speak. We have asked everybody to try and limit your
21 remarks to five minutes, and we will accept any additional
22 comments, written, for the record.

23 We will then go through out side quickly and pose
24 questions from FDA, and then will proceed from one panel to
25 the next with some limited breaks and so on and so forth.

1 Let me just see if--there were some notes that I
2 wanted to be sure we got to. Did you do the logistics, such
3 as where the restrooms are and those sorts of this?

4 MR. HUBBARD: No, we didn't do that.

5 MR. LEVITT: Well, let me do--If you'll allow me
6 one more minute, we'll get to the really important stuff.

7 The rest rooms are on the left and right of the
8 main corridor. When you go out, turn right when you leave
9 the auditorium to get to the main corridor.

10 Number two: food. Some people will get hungry
11 today. There is an express cart with coffee and snacks that
12 is located right out there. I saw it just when I ran in.
13 That will be available until noon. Just before noon we'll
14 talk about luncheon arrangements.

15 Number three: panelists for the morning should be
16 seated in the reserve section in the front of the podium
17 over there. So, hopefully, the other people sitting over
18 there are the people who are going to speaking later this
19 morning. In the afternoon, the same way. That will help us
20 as we try to get up and down. And, as you see, the
21 logistics for just getting up and down are challenging in
22 and of themselves.

23 As I said, we'll allow five minutes per speaker.
24 We do have somebody who's going to help us in timing.
25 Ellen? Show us where Ellen is, thank you. We will have a

1 one-minute warning, and a still friendly orange time, which
2 is a nice way of saying time is done. And we would ask you
3 to respect that. I know I was giving a speech yesterday, and
4 all of a sudden--it was a 25 minute speech, and the 5-minute
5 sign went up, and said, "Holy smokes," and I had to adjust
6 myself a little bit, but was able to finish. So we all need
7 to live with that.

8 As I said, we do have a full agenda, and we need
9 to deal with that.

10 I'll talk about luncheon later.

11 Finally, a couple of concluding remarks. And,
12 again, if this was covered before, I apologize. We made a
13 mistake in the Federal Register notice on the closing date
14 for comments. We meant to say August 20th for the date for
15 comments due, instead of the earlier date. That was clearly
16 as mistake.

17 Number two: the slides I just showed are available
18 in today's handouts and on our Web site.

19 Number three: if you want written requests for the
20 meeting transcript, the meeting is being transcribed. You
21 can ask FDA's FOI office. Give us two weeks, please, or 15
22 days, it actually says here. And the address of the office
23 is on the back of the Federal Register notice. And I
24 mentioned the similar meeting in California.

25 Now, somebody also handed me something here that I

1 think I'm supposed to say, so let's see.

2 [Pause.]

3 Okay. I think these items have essentially be
4 covered.

5 With that, I will take a deep breath, try and sit
6 back and relax, and if we can figure out the lights and the
7 logistics, we will proceed to the first panel. And my list
8 says that Dr. Lucinda Maine, Senior Vice President
9 Professional Affairs, APhA is our first speaker, and she is
10 standing at the podium, ready.

11 Thank you. If we can turn this off, we can focus
12 attention on you. Thank you very much.

13 Please, Dr. Maine.

14 **PANEL I - TRADE ASSOCIATIONS**

15 DR. MAINE: Yes. Thank you for the opportunity to
16 provide input to the Center on how you can best develop an
17 overall strategy for achieving effective regulation of
18 dietary supplements.

19 I do represent the American Pharmaceutical
20 Association, the national professional society of
21 pharmacists, with over 210,000 pharmacists, scientists,
22 students and technicians.

23 I'll briefly address your key questions, first by
24 sharing where the Association finds itself with respect to
25 policy development on what we believe is one of the most

1 profound examples of consumerism in health and wellness.
2 Then, drawing on the results of recent focus groups held
3 with pharmacists, I'll share our perspective from a key
4 health care provider that hopefully will guide the agency as
5 you struggle with these important questions.

6 We are respectful of the constraints on the agency
7 from public pressure to keep dietary supplements in a
8 largely unregulated environment. I personally had begun to
9 wonder whether a contributor to this consumer opinion is the
10 fundamental belief held by consumers that an acceptable
11 threshold of regulation on these products currently exists.

12 These products appear on the shelves of our
13 nation's pharmacies where many other categories of
14 traditionally regulated products are found. Consumer belief
15 would be supported by the history of strong regulation by
16 this agency for the full range of products currently and
17 clearly in your jurisdiction.

18 Our association initiated policy development on
19 these products in 1997, per the request of both our
20 practitioner and science members. Ultimately, five
21 suggested policies came before our house, and that related
22 to the need for informed decision-making pharmacists and
23 public; the need for additional sources of quality education
24 and publication for practitioners; suggestions that
25 manufacturers provide evidence of the use of good

1 manufacturing practices; and the adherence to standards and
2 quality control sufficient to ensure that only quality
3 products are available for sale to the public.

4 I believe reflective of the evolution in
5 pharmacists at the time, the house overwhelmingly adopted
6 the policy stating that informed decision-making should be
7 the basis what pharmacists and consumers do, and that APhA
8 needed to provide pharmacists assistance, in terms of
9 education and publications to facilitate their counseling of
10 patients on proper use, indications, safety and interactions
11 between these and other products. Deferred were the
12 policies on what the profession should require from
13 manufacturers and suppliers of these products in terms of
14 standardization and assurance of quality.

15 Two years later pharmacists find themselves
16 increasingly called upon to provide consumers information
17 regarding the use of these products. APhA's education and
18 publications efforts have expanded during this timeframe in
19 response to great demand from our members to provide the
20 most credible information possible. A continuing challenge
21 to the Association and to pharmacists is the lack of
22 information on efficacy, safety, standard dosage, side
23 effects and interactions with traditional therapies and
24 conditions. This information is that which pharmacists and
25 other health care providers have come to use and find easily

1 available for traditionally regulated products. APhA will
2 again be focusing on the development of meaningful policy
3 specific to the regulation of these products over the next
4 nine months, and we welcome input from FDA and key
5 stakeholders as we embark on this path.

6 Findings from two focus groups of pharmacists
7 recently conducted by APhA provide additional guidance to
8 your key questions. Pharmacists are using a variety of
9 terms to define this category, and their terms do differ
10 from those used by consumers, in many cases. The key issue
11 for pharmacists is determining the quality and efficacy of a
12 supplement. Pharmacists that all types of consumers are
13 approaching them seeking information regarding the purchase
14 of these products. Often it appears that the consumer is
15 seeking to establish credibility to a decision that they
16 have reached based on advertising, consumer media and word
17 of mouth recommendations from friends, family and others.

18 Pharmacists do want manufacturers to prove the
19 quality of their products using means similar to the trusted
20 approach for pharmaceuticals--controlled clinical trials
21 with results disseminated and peer reviewed in reputable
22 publications. And pharmacists want to see standards
23 established for this category of products.

24 The current scientific and regulatory environment
25 for dietary supplements is clearly insufficient. One area

1 for research that the FDA could embark upon would be the
2 ability of these products to actually deliver the intended
3 substance. Recently publish research in our journal The
4 Journal of the American Pharmaceutical Association, has
5 indicated problems with, for example, dissolution. The
6 product was--the publication was entitled "The Comparison of
7 Melatonin Products against USP's Nutritional Supplement
8 Standards," and we did find that not all products dissolved
9 according to the USP specifications.

10 I will close with my recommendations, and there
11 are four.

12 There is a need to establish what consumers
13 believe is the current regulatory framework for dietary
14 supplements. I think this speaks to your "boundaries."

15 There is a need to clarify the nomenclature and
16 criteria for classification of products.

17 A systematic process for aggregating and applying
18 the most credible evidence is required.

19 And I believe adverse event reporting for these
20 products should be integrated into existing systems and
21 systematically analyzed, with that information being fed
22 back to consumers.

23 Thanks again for the opportunity to participate in
24 today's panel.

25 MR. LEVITT: Thank you very much.

1 Our next speaker is William Soller, from CHPA.
2 And, Bill, I won't take this out of your time, but as you're
3 standing up there and getting ready--I neglected--I saw you
4 over there, and I just assumed you were on the list--but
5 Michael Ford is not on the written agenda, but he's sitting
6 up here and will be one of the speakers of this panel, and
7 we certainly welcome you here, too.

8 Please, Dr. Soller.

9 DR. SOLLER: Good morning. I'm Dr. Bill Soller,
10 Senior Vice President and Director of Science and Technology
11 for the Consumer Health Care Products Association, which
12 represents producers of quality dietary supplements and non-
13 prescription medicines, including over 200 member companies
14 across the manufacturing, distribution, supply and service
15 sectors of the self-care industry.

16 We have detailed written comments that supplement
17 these oral remarks and have been put into the record today.

18 In setting its priorities, CFSAN should place
19 safety first; that is, enforcement, GMPs, and AERs, as well
20 as the development of a three to five year detailed
21 strategic plan or gaps analysis. While activity in the
22 claims area may proceed as priority is given to safety
23 issues, its completion should be targeted farther in the
24 future than that for resolving the safety-related issues,
25 and I have six points.

1 First, in passing DSHEA, Congress intended that
2 consumers would use dietary supplements for health
3 promotion, health maintenance, and disease risk reduction.
4 Consumer confidence is essential to product use.
5 Allegations that the dietary supplement industry is
6 unregulated or that FDA does not have sufficient enforcement
7 powers, which it does, acts to undermine consumer
8 confidence. Therefore, foundational to CFSAN's overall
9 strategy for dietary supplements is an effective enforcement
10 policy that removes unsafe products from the marketplace and
11 that ensures truthful, not misleading, and substantiated
12 claims on dietary supplements. Because of the complementary
13 jurisdiction of FDA and FTC in this area, the two agencies
14 must coordinate closely, and a public workshop on this
15 matter would be helpful for all stakeholders to understand
16 the current relationship between these agencies.

17 Second, the dietary supplement industry has
18 maintained that specific GMP regulations would be helpful
19 for ensure that dietary supplements are safe and not
20 adulterated or mis-branded; have the identify and provide
21 the quantity of dietary supplement ingredients declared in
22 the label; and meet the quality specs that the product is
23 represented to meet. We recommend that FDA make the
24 publication of proposed GMPs a top priority in 1999, and
25 consider the additional comments that we have developed and

1 appended to our written comments.

2 Third, as outlined in our remarks to the House
3 Committee on Government Reform on May 27, we recommend that
4 CFSAN prepare a written plan for, and adopt a systems
5 approach for AERs similar to that recommended in FDA's May
6 1999 "Managing the Risks for Medical Product Use: Creating a
7 Risk Management Framework." We think the system should be
8 grounded in the Agency's current safety policy and have
9 specific refinements to CFSAN's current AER surveillance of
10 dietary supplements, such as defined protocols for
11 consistent handling of AERs, training and re-examining AER
12 listing on the CFSAN Web site, etcetera.

13 Fourth, boundaries between different types of
14 products--drugs, conventional foods, dietary supplements,
15 and cosmetics--should be based on a product's claim which
16 defines the intended use of the product. In this way, a
17 product may have more than one intended use which should not
18 be considered an overlapping situation, but rather one that
19 is coexistent. Importantly, because the two major
20 confounding issues in FDA's structure/function proposal
21 related to the overly broad redefinition of "disease," and
22 the intricate interrelationship between health promotion
23 maintenance and disease prevention, we recommend that FDA
24 re-propose its structure/function proposed rule as a
25 focused, regulatory statement that closely incorporates the

1 intent of DSHEA, amends FDA's proposed redefinition of
2 "disease," as we proposed in our comments; omits the
3 confusing and ambiguous proposed criteria; and addresses
4 implied claims by the statutorily required disclaimer on
5 structure/function claims.

6 We also recommend development of a guidance on
7 structure/function claims for dietary supplements consistent
8 with DSHEA, and modeled after the FTC advertising guidance
9 to industry.

10 Fifth, we don't recommend--we do not recommend
11 that CFSAN move forward at this time with the appointment of
12 a formal dietary supplement advisory committee. CHPA
13 considers the priorities of safety, an overall strategic
14 plan or gaps analysis and claims policy of sufficient
15 potential resource intensity that the appointment of another
16 special advisory committee, in a formal sense, would detract
17 at this time from the needed refinements in CFSAN's
18 operations and activities. The operational mechanism of
19 special working groups, as needed, on the Foods Advisory
20 Committee appears to be working, given the nature and extent
21 of the agenda for dietary supplements at this time.

22 And, finally, industry has an interest in helping
23 to ensure that FDA is appropriately staffed and funded to
24 meet its statutory obligations of promoting and protecting
25 the public health. Only if we know and contribute to the

1 three to five year plan or gaps analysis for CFSAN are we
2 able to knowledgeably pursue appropriations requests to
3 build the CFSAN infrastructure needed for dietary
4 supplements, hence the importance of what comes out of
5 today's meeting.

6 Thank you very much.

7 MR. LEVITT: Thank you very much.

8 Our next speaker is from the National Food
9 Processors Association, Regina Hildwine, Director, Food
10 Labeling and Standards.

11 MS. HILDWINE: Good morning. I'm very grateful
12 for this opportunity to present NFPA's views.

13 NFPA--National Food Processors Association, is the
14 principal scientific trade association representing the food
15 processing industry. There are copies of my remarks out on
16 the desk. We are going to file written comments at a later
17 date.

18 Today I'm very briefly going to discuss issues
19 related to safety and labeling claims, and I'm going to
20 bring in some things relative to other classes of foods.

21 NFPA is interested in dietary supplements because
22 they are foods. NFPA supports a regulatory policy which is
23 consistent for all foods with respect to safety and label
24 claims. NFPA also believes that safety comes first. NFPA
25 is aware that the law makes different provisions for the

1 burden of proving safety of ingredients for dietary
2 supplements and for other foods. While, by law, dietary
3 ingredients of dietary supplements are no longer deemed to
4 be food additives, NFPA believes that this does not absolve
5 the dietary supplement industry from responsibility for
6 safety of their products and ingredients. Dietary
7 supplement companies should continue to assess the safety of
8 their products and ingredients prior to market, monitor
9 safety after market introduction, and have procedures in
10 place in the event a recall is necessary. Dietary
11 supplements are not exempt from voluntary recall provisions.

12 To assist the dietary supplement industry in
13 assuring the safety of its products, NFPA believes that FDA
14 should proceed promptly with the rulemaking of good
15 manufacturing practices--that is, GMPs--for dietary
16 supplements. We see this as a top priority. The experience
17 of the food industry is that FMPs serve as a useful outline
18 for those production and processing procedures which result
19 in safe and high quality food products.

20 The dietary supplement industry should also be
21 encouraged to notify FDA that key dietary ingredients of
22 their products are generally recognized as safe--that is
23 GRAS--especially dietary ingredients with some history of
24 use. We see this as another objective that should be
25 considered. Using GRAS notifications for dietary

1 ingredients with a history of use would complement the
2 current pre-market notification procedures for new dietary
3 ingredients or dietary supplements. GRAS substances are not
4 food additives by legal definition, so dietary supplement
5 ingredients would not be excluded from consideration under
6 GRAS provisions. Ingredients of dietary supplements should
7 be help to the same GRAS standard as conventional food
8 ingredients.

9 Consideration under GRAS provisions should address
10 current levels of consumption and conditions of use for
11 dietary ingredients, including herbals and botanicals.
12 Current uses may be very different from historical uses.

13 We note that some botanical ingredients have
14 utilized the new GRAS notification process, however their
15 notified as "flavors." To assist the dietary supplement
16 and, indeed, all sectors of the food industry, NFPA
17 recommends that FDA should promptly finalize its proposed
18 GRAS notification process. The supplement industry should
19 then be encouraged to use this provision to ensure that the
20 users of supplement ingredients, including herbal and
21 botanical ingredients that there is no question of the
22 safety of these substances.

23 NFPA believes that the dietary supplement industry
24 should carry the burden of ensuring its products are safe,
25 and FDA should provide a regulatory environment, through

1 GMPs and GRAS, to assist the industry in its endeavors.

2 Regarding label claims of health benefits,
3 conventional foods and dietary supplements enjoy similar, if
4 not always identical, regulatory approaches--and I talk a
5 lot about this all over town. In the area of health claims,
6 both conventional foods and dietary supplements should be
7 subject to the same provisions, and this includes extending
8 FDAMA health claims provisions ultimately to supplements.
9 NFPA also believes that the recent court decision in Pearson
10 v. Shalala ultimately will exert equal force on claims
11 labeling rules for both dietary supplements and conventional
12 foods.

13 With respect to structure/function claims, NFPA
14 commented last year that FDA's unfortunate proposed rule
15 would have as much of an adverse effect on claims for
16 conventional foods as it would on dietary supplements. The
17 proposed redefinition of disease would adversely affect
18 health claims and structure/function claims across the
19 board.

20 NFPA has urged FDA to withdraw this proposal and
21 we repeat our request today. We also ask FDA to take to
22 heart the arguments we put forward with respect to nutritive
23 value.

24 It's imperative that all types of claims on all
25 foods, including dietary supplements be well substantiated

1 or fairly carefully and explicitly qualified. We believe
2 that FDA needs to be aggressive in its enforcement posture
3 against any poorly substantiated, poorly qualified or
4 otherwise misleading claims. And we also urge FDA to work
5 in cooperation with the Federal Trade Commission.

6 All these reforms--safety and claims--are needed
7 not only to ensure a level playing field between dietary
8 supplements and conventional foods, but to prepare a
9 positive environment for new types of foods being designed
10 to provide health benefits beyond those of basic nutrition.
11 Whether these novel foods or dietary supplements in the form
12 of conventional foods, or traditional foods enhanced with
13 properties or components associated more with dietary
14 supplements, NFPA believes that the course to a barrier-free
15 regulatory environment lies in correcting the flaws in
16 current rules and a strong enforcement approach, rather than
17 embarking on a new regulatory scheme.

18 Thank you very much.

19 MR. LEVITT: Thank you.

20 Next we'll hear from Dr. Annette Dickinson,
21 Council for Responsible Nutrition.

22 DR. DICKINSON: The Council for Responsible
23 Nutrition is a trade association of the dietary supplement
24 industry, representing approximately 100 member companies,
25 ranging from suppliers of raw ingredients to finished

1 product manufacturers; manufacturers of national brands as
2 well as store brands; and manufacturers of products which
3 are marketed through all channels of distribution, including
4 mass market, health food stores, direct sales and mail
5 order.

6 We are encouraged by FDA's state commitment to an
7 open and participatory process, but we hope--and, in fact,
8 we have confidence--that that process will, in fact, go
9 beyond what is possible in this meeting which was,
10 unfortunately, announced with less than 30 days' of notice,
11 and permits only five minutes per presentation. So we look
12 forward to additional discussions in the future.

13 FDA indicates that the two primary objectives for
14 its dietary supplement strategy are to assure consumers of
15 safe dietary supplements, and to assure consumers that
16 labeling is truthful and not misleading. We fully support
17 these two objectives, but we would urge FDA to add a third
18 overall objective to this plan, and that is to fully
19 implement DSHEA.

20 FDA may currently be of the opinion that this is
21 implicit in its strategy, but we believe it needs to be made
22 explicit and, in fact, we believe the most critical issue
23 facing FDA and the industry today is the perceived failure
24 to implement DSHEA, which leads to the inappropriate
25 conclusion that FDA lacks authority to regulate these

1 products when, in fact, the issue--as has been mentioned
2 already--is more enforcement and implementation.

3 We believe that all of the elements of the overall
4 strategy can be encompassed in three headings: one for
5 safety, which actually is not a current heading in the
6 proposed outline--one for safety and one for GMPs. Under
7 the issue of safety, FDA needs to address--continue to
8 address--the issue of new ingredients of dietary supplements
9 and also adverse event reporting. We fully support FDA's
10 continued review and action on new dietary ingredients
11 notifications, and have supported FDA action that has been
12 taken earlier this year. However, we have been disappointed
13 that in one case involving GBL FDA's action was based on a
14 new drug--unapproved new drug theory, rather than relying on
15 the provisions of DSHEA directly as the basis for
16 enforcement action.

17 We also support the need for prompt and effective
18 adverse event reporting, and the current system needs
19 improvement, because it is not prompt and it puts companies
20 at a risk of having a product falsely associated with an
21 adverse event.

22 We have suggested a number of specific
23 modifications to the adverse event reporting system in our
24 written statement provided today, and we will expand on that
25 in our final statements before this is over. This include

1 involving companies directly in evaluating adverse events;
2 evaluation reports with regard to the strength of
3 association; correcting errors that may have appeared in
4 public reports; and carefully considering whether there is,
5 in fact, a role for specific identification of companies and
6 products. In looking at some previous FDA adverse event
7 reporting systems on food additives and other ingredients,
8 in general, specific company and product name is not
9 included in the overall report.

10 On the issue of claims, FDA has a number of issues
11 facing it, including statements of nutritional support, NLEA
12 health claims, and FDAMA health claims. We encourage FDA to
13 rely specifically on DSHEA for the definition of statements
14 of nutritional support and to recognize that the only
15 dividing line provided by DSHEA between statements of
16 nutritional support and disease statements is the specific
17 mention of a disease condition. We would urge the agency to
18 withdraw the proposal that was published last year, and to
19 implement--simply proceed with implementing DSHEA on this
20 point.

21 On NLEA health claims, we would encourage FDA's
22 review and approval of four new petitions that have been
23 filed or will be filed in the next week or so, and to
24 implement the requirements of the Pearson decision, if
25 necessary, in evaluating those petitions.

1 We also encourage FDA to fully implement the FDAMA
2 health claims provisions, using the criteria that are
3 specified in the Act, and without adding new requirements
4 which are not included in the law itself.

5 On the issue of GMPs, we join the previous
6 speakers in urging that FDA make the completion of the GMP
7 process a very high priority. We and our members who
8 prepared and submitted the drafts on which the current
9 proposal is based stand ready to provide any additional
10 assistance that we can provide in moving that process
11 forward.

12 My final two points regarding leveraging of
13 resources and stakeholder involvement: FDA needs to leverage
14 its resources, and we believe that one of the ways to do
15 that is to appoint a dietary supplement advisory committee
16 to help review important issues relating to this product
17 category. In the meantime, FDA needs to continue to rely on
18 working groups to supplement the existing Food Advisory
19 Committee, which does not have the expertise in our product
20 category. At this time, we call on FDA specifically to
21 appoint dietary supplement industry liaison members to the
22 existing Food Advisory Committee, and also to any dietary
23 supplement advisory committee that may ultimately be
24 established.

25 The industry wishes to be involved with FDA as a

1 major stakeholder in regulating this product category. We
2 believe in the importance of private-public partnerships,
3 and we are prepared to work with FDA to improve mutual
4 communication and action. Often, when serious issues arise,
5 we learn about it only hours before a public announcement is
6 made. We want to be a more meaningful partner with you in
7 resolving solutions to those problems, whenever possible.

8 Thank you.

9 MR. LEVITT: Thank you very much.

10 Next, we have Dr. Maureen Mackey from RDIA.

11 DR. MACKEY: Thank you for the opportunity to
12 speak today on behalf of the Research-based Dietary
13 Ingredient Association, which is an association of companies
14 including Cargill, Galogen, Monsanto and Novartis, committed
15 to championing the role of science in the development² of
16 functional food ingredients and related products.

17 Our comments today are directed towards the
18 agency's request for input on its objectives to ensure
19 consumer access to safe dietary supplements that are
20 truthfully and not misleadingly labeled. We also will
21 address the agency's request for guidance in developing
22 implementation strategies that leverage its limited
23 resources.

24 RDIA urges FDA to develop a regulatory framework
25 for foods and dietary supplements that, first, has

1 consistent and transparent standards for safety and claims
2 substantiation; has timely and predictable processes for
3 regulatory acceptance; and, thirdly, rewards investment in
4 research. I'll first talk about standards for safety.

5 As we would all agree, consumers have the right to
6 know that the foods and dietary supplements they consume are
7 safe. These products should meet a common safety standard
8 that their consumption will not pose a significant or
9 unreasonable to health when used as intended. Meeting this
10 standard may require a scientific process that includes
11 original research. For example, if the safety assessment of
12 a new dietary ingredients in a dietary supplement indicates
13 that the safety standard articulated above cannot be met
14 through experience based on common use and published
15 literature, then safety research will be required. We
16 believe there is a need for uniformity of understanding in
17 the industry as to what the safety standard means, and what
18 information is required to be assured the standard is met.
19 While DSHEA does not prescribe the specific safety-
20 assessment process, neither does it excuse any company from
21 determining that its products are safe for the target
22 population at the specified level of ingestion. We urge FDA
23 to work with industry to help assure uniformity in
24 understanding what information and science are required to
25 meet the safety standard as indicated under the law.

1 Second, standard for claim substantiation. RDIA
2 believes that foods and dietary supplements whose benefits
3 to health have been demonstrated via sound scientific
4 research to a reasonable certainty should be able to
5 describe these benefits on labeling, whether a
6 structure/function claim, NLEA health claims or FDAMA health
7 claims. The nature of the science needed to support a claim
8 likely will vary, depending on the type of claim made, but
9 the same standard of reasonable certainty that the claim is
10 truthful and not misleading should be required. We
11 encourage FDA to apply this standard evenly to all types of
12 claims on both foods and dietary supplements.

13 One of the obstacles to developing responsible
14 claims for products is the lack of clarity regarding the
15 nature and extent of evidence constituting adequate
16 substantiation. We realize it is not feasible or even
17 desirable to prescribe a set of studies needed to
18 substantiate every claim. However, we believe it is
19 appropriate to establish a process for gathering, evaluating
20 and weighing the evidence that may substantiate a claim, and
21 to require that this process be applied consistently. We
22 would bring your attention to the Functional Foods Technical
23 Committee of the International Life Sciences Institute,
24 which is developing a proposal for such a process, and is
25 seeking scientific input and acceptance. RDIA supports this

1 effort and believes it will help assure that claims are
2 evaluated according to a consistent, scientifically sound
3 process.

4 Third, I'll talk about timely and predictable
5 processes for regulatory acceptance. RDIA believes there
6 should be mechanisms in place to assure that claims made on
7 foods and dietary supplements do, in fact, meet a standard
8 of reasonable certainty, and that they can be used by
9 manufacturers within a timely manner after their data
10 evaluation is complete. RDIA believes it makes sense for
11 industry to participate actively in its own monitoring. For
12 example, industry could develop guidelines that would help
13 its members perform appropriate and adequate studies to
14 assure reasonable certainty. In addition, an independent
15 expert review process could be established to verify that
16 claims are substantiated. This option would take much of
17 the burden of data evaluation off the FDA. These measures,
18 however, are not meant to replace FDA's role and authority
19 in taking action against claims. Rather, they would limit
20 the number of situations in which FDA would need to act.

21 And, lastly, incentives for investing in research.
22 RDIA believes the regulatory system should be designed and
23 implemented in a way that encourages research and
24 development of products that benefit people. For example,
25 suppose a manufacturer of a dietary supplement invests

1 significantly in well-conducted clinical studies to
2 demonstrate its product reduces blood cholesterol
3 consistently in subjects with moderately elevated
4 cholesterol, when taken as part of an overall dietary plan.
5 The current petition and approval process for health claims
6 under NLEA is too uncertain and time-consuming, and the
7 provisions that data supporting a health claim be publicly
8 available, and that any company can use an approved claim,
9 are strong deterrents to research investment. Instead, the
10 manufacturer should be rewarded for its investment by having
11 the freedom to make a labeling claim, such as "When taken as
12 part of an overall dietary plan, this product can help lower
13 moderately elevated cholesterol levels." Such a claim
14 should be allowed, because that is what the data truthfully
15 and not misleadingly showed. We realize some of our
16 proposed objectives require legislative change. In the
17 meantime, RDIA urges the FDA to step back from its current
18 view on claims and generate discussion within the scientific
19 and public health communities and industry on how the
20 results of scientific studies about products should be
21 presented appropriately to consumers.

22 Thank you.

23 MR. LEVITT: Thank you very much.

24 And, again, our final speak on this panel is
25 Michael Ford from NNFA. Again, I apologize for not having

1 your name on the written agenda.

2 MR. FORD: Okay. Well, thank you very much for
3 accommodating me. I do appreciate it, and we appreciate
4 this series of hearings.

5 We agree with the three identified themes of
6 maintaining a credible FDA program, and maintaining a
7 science-based program with highly qualified scientists, and
8 maintaining FDA's importance to consumers in the regulated
9 agency, but we want you to act. We need you to get off of
10 the thematic and on to the schematic, so to speak.

11 With the issues that you have identified, with
12 respect to claims, we would agree with you. While maybe you
13 haven't stated this publicly, but we believe there's a great
14 deal of fraud in the claims in the marketplace. And the
15 only answer that there is for dealing with that fraud is
16 enforcement of DSHEA. It is your only course.

17 We believe that structure/function statements, as
18 described in the law, are quite broad in scope and there is
19 not a need to make medical-style claims. We believe that
20 the structure/function statements afford the industry ample
21 opportunity to expand their markets. But you must enforce--
22 you must see the substantiation for these claims, because if
23 you don't, then the fraud will continue. And DSHEA gives
24 you the tools that you need to take care of business.

25 As far as defining the boundaries--all the -

1 ceuticals that are out there: the neutraceuticals, the
2 cosmeceuticals--you have a lot on the table to deal with.
3 And we suggest that you consider the appointment of expert
4 advisory group--not necessarily, perhaps, through the
5 Advisory Committee Act, but more of an ad hoc but standing
6 group that could combine the best from academia, consumer
7 groups, industry, congress and, of course, the FDA, to help
8 you through some of these issues where I think that you do
9 need assistance.

10 I agree with what's been stated today that GMPs
11 are extremely important. We believe the ANPR that came out
12 was a little more drug-like than perhaps intended, even
13 though it came substantially from the industry. I believe
14 the industry has moved along, the technology has moved
15 along. We are moving along, also. And yesterday NNFA³
16 completed its first inspection of a member company. As I've
17 said here before, we now have mandatory GMP compliance--GMPs
18 that we have put together--for continuing membership in the
19 Association. And we hope to have the opportunity to sit
20 down with you and talk with you more about that, and even
21 invite you on some of the inspections and see the process
22 that we are using.

23 With the adverse event reports, obviously there's
24 a lot of improvement needed. I want to stress here today
25 that NNFA has not supported any of the arbitrary efforts

1 budgetarily or legislatively to undermine the AER safety
2 issues. We want to work with you to get the AER program the
3 way it needs to be but, let's face it, when we're talking
4 AERs--we're talking ephedra--you truly need to move, again,
5 on your regulation. We believe that perhaps you didn't go
6 the right way with your regulation. We have suggested a
7 guidance. But if you feel strongly that you went the right
8 way, based on your AERs, then go ahead and finalize it. If
9 the industry believes that you've not met your burden of
10 proof, then I guess it will be worked out in court. But I
11 think that would be a reasonable move at this point, rather
12 than continuing with what kind of tends to be a rope-a-dope
13 strategy, that the fraud in the industry, and the injuries
14 in the industry are just going to do the industry in
15 ultimately if you stand by. Don't stand by. Act.

16 I think that the responsible part of this industry
17 wants rules, and they just want to know what they are. They
18 want to play by them if they know what they are.

19 As far as the research needs, I think the FDA has
20 mighty research needs. We support a science-base for claims
21 and for regulations. Hopefully, there's room for
22 collaboration with the Office of Dietary Supplements and the
23 Center for Complementary and Alternative Medicine when it
24 comes to the products in our area.

25 My main message--well, I do want to get to

1 resource needs. We think the industry is trying to help you
2 out with some meaningful self-regulation but obviously you
3 need more dough to serve the public well on the safety
4 issues, and to enforce against the outliers. And that's what
5 I suggest that you do to use your money wisely is stop
6 trying to get most of the mainstream companies that are in
7 the sort of a gray area, go after the outliers--I think we
8 all know who they are; they're making outrageous claims--you
9 could use your resources better. If we knew what an
10 adequate budget would be for you to enforce DSHEA
11 adequately, we would probably advocate for that on the Hill
12 for you, which would be an unusual situation but something
13 we would jump right into.

14 Please use your authority--base your decisions on
15 law and science. You will find that you do have industry
16 support.

17 MR. LEVITT: Thank you very much.

18 What we'll now do--and this will be our first try
19 at this, so we thank you for being the test--the focus group
20 for us. What we're going to try to do is, I think, as each
21 of the FDA panelists to ask one question, and then we'll see
22 where we are on time. But we'll probably then be moving to
23 the next panel.

24 So, I'll go first and the others can be sitting
25 here thinking of what your question is.

1 My question relates to the general issue of how we
2 get outside advice into the process. CRN has been very
3 forceful and consistent in advocating a separate advisory
4 committee, and has recently submitted a written proposal on
5 that subject. CHPA thought that that was not the right
6 approach, and has an alternative. Over here we had yet a
7 third alternative. There was a fourth idea for leveraging
8 outside help. How do we make sense of this? You've all
9 each other. You talk to each other. Just kind of quick
10 thoughts down--or is this just something--FDA should hear
11 all the views, make a decision and move on, kind of based on
12 your last point?

13 MR. FORD: Well, we've been talking--

14 MR. LEVITT: You need to speak into the mike, and
15 we can pass the mikes down the table, as needed.

16 MR. FORD: Okay. We've been thinking about this
17 advisory committee issue for a long time, and we're probably
18 more in agreement with CRN than with other groups, that
19 there needs to be a group you can turn to. But our thinking
20 has progressed somewhat, and wonder if the bureaucracy and
21 expenditures that would be associated with appointing a
22 committee through the Advisory Committee Act is necessary,
23 in terms of getting the expertise that you need. I think
24 that's what you really need is the expert advice, more than
25 something--a body to make regulatory decisions for you. So

1 we're looking at the idea of a voluntary group that would
2 have some substance, from a variety of sectors, that could
3 help you through a lot of the bumpy roads ahead.

4 DR. MACKEY: We like the GRAS notification process
5 quite a bit; the assembling of private experts to evaluate
6 your data product by product. We also think that a similar
7 process could be developed for claim; if you wanted an extra
8 measure of credibility behind your claim, that an
9 independent body--we've suggested something like the Life
10 Sciences Research office--could be commissioned to undertake
11 this kind of thing. It would be voluntary, but you could
12 distinguish your claim somehow on labeling.

13 DR. DICKINSON: We think the priority is for FDA
14 to have access to the right experts as it goes about making
15 these decisions. As you say, we have supported a formal
16 dietary supplement advisory committee. In the process of
17 developing that--and we understand that it can sometimes
18 take a year or more to develop--in the process of developing
19 that, or even if you decide not to develop that, we think
20 that the immediate priority is to get that kind of expertise
21 available to you through the Food Advisory Committee, which
22 you are already using to refer many of these questions to,
23 by outside working groups such as those you have already
24 convened, but possibly by additional ones of those, and by
25 incorporating into that committee representatives of the

1 affected industry and other interests who are involved in
2 the dietary supplement business. I think that's the
3 immediate priority for purposes of dealing with issues that
4 are on the table right now today as you move forward in
5 considering the value of a separate committee.

6 MR. LEVITT: Okay. Thank you.

7 Regina?

8 MS. HILDWINE: Well, we didn't talk about this in
9 our prepared remarks. Certainly, NFPA believes that any
10 point at which FDA interacts with outside organizations has
11 to be publicly transparent. And we believe that that is the
12 protection afforded by the Advisory Committee Act. The
13 exact mechanism that you use--I think you're going to have
14 to figure out what works best, but I believe that the APA is
15 going to give protections relative to transparency and
16 public process, and that's very much needed in this area.

17 MR. LEVITT: Bill?

18 DR. SOLLER: Yes, just a quick comment.

19 Our thought here really is on the operant word "at
20 this time." And we look at this in regards to priorities
21 that you have, and as we've kind of looked at this
22 landscape, we see enforcement GMPs and AERs as being the top
23 priority issues, and then over a longer term, probably the
24 claims situation playing out. So, you know, the operant
25 word being "at this time."

1 MR. LEVITT: Excuse me, Bill. Does that mean that
2 you see the proposal for an advisory committee as relating
3 primarily to claims, and not to GMPs, AERs, etcetera?

4 DR. SOLLER: I was just getting into that.

5 What I was saying is that as we look at this and
6 think about the sort of building the infrastructure within
7 Special Nutritionals and CFSAN, versus some sort of claims
8 review--and let me just return to that in a moment.

9 The infrastructure on AERs and GMPs, just given my
10 experience with advisory committees, both on the RX and the
11 OTC side, is that you're not necessarily going to get the
12 expertise out of academia that has dealt with GMPs and AERs
13 in a particular product category. And that's building the
14 basic infrastructure. So the kind of working group approach
15 that's been used with the Food Advisory Committee, that has
16 very heavy industry input when you look at it, compared to
17 other types of working groups, is more along the lines of
18 what Michael Ford was saying as something other than a
19 formal advisory committee.

20 Now, as you get into the claims area, and you
21 think about botanical drugs and the sorts of things that are
22 going to come out of NIH, and potentially go for either an
23 RX, and RX to OTC switch, or and OTC drug type of claim--and
24 that is a possibility--we have, of course, the
25 Nonprescription Drug Advisory Committee that, under its

1 purview, does have botanical drugs--senna, cascara, sagrada,
2 and psyllium and so on--so it's not foreign to that area.
3 But you made need special botanical expertise as you explore
4 that in the initial period.

5 I think, as you get into DSHEA type claims and
6 structure/function claims, that could be a morass, in terms
7 of a formal advisory committee, and could be less productive
8 than going after the outliers, as was suggested by Michael
9 Ford earlier. And I think that is how, in looking at an
10 advisory committee, you have to think about where your
11 priorities are, and then what type of groups do you really
12 need in to give you advice. And on AERs I would ask: would
13 not CDER be a very important, and perhaps the primary focus
14 that you want to work with, particularly with respect to
15 Jane Henney's May '99 publication, which is a very, very
16 important document for you to look at in the AER sector.
17 And I would say maybe you don't need that much input from
18 outside groups on some of these issues.

19 MR. LEVITT: Do you have anything to add?

20 DR. MAINE: Just very quickly--we don't have a
21 formal position on an advisory committee. I think what
22 you'd needed to do, though, is set as efficiently as you
23 can, a table that brings together the broadest community of
24 interest, with the credible scientists, the provider
25 community, the industry and consumer interests reflected, so

1 that the dialogue that needs to occur can occur, but again
2 in a way that doesn't hamper the agency from moving forward
3 on its priorities.

4 MR. LEVITT: Okay. Let me turn to Margaret
5 Porter.

6 MS. PORTER: The question I have relates to safety
7 and ADRs, and I know a number of the panel has indicated the
8 importance of an adequate ADR system in assuring the safety
9 of dietary supplements. And I now that several of you have
10 said you're going to submit additional comments for the
11 record on this. But I'd be interested just in this context,
12 if any of you would address sort of what you see as the
13 relative responsibilities and abilities of various
14 stakeholders in the system, whether it's consumers,
15 manufacturers, retailers, health professionals, the Agency,
16 in terms of identifying information on adverse events,
17 reporting that information and monitoring it?

18 DR. MAINE: I would just start with identifying
19 the fact that I think we have no good model for adverse
20 event reporting in the full range of products that I would
21 classify as pharmacotherapies, and I include these in that.

22 I am respectful--tomorrow there's an excellent
23 meeting, for instance, that's being held on this topic
24 specifically. And I think that the reporting mechanisms
25 have to be evolved so that simple reporting, but meaningful

1 reporting, is available from everyone: consumers, providers,
2 and all other stakeholders, but that it has to go into an
3 intelligent system that will analyze that information so
4 that it is not spurious, it's not misleading, and that it
5 can really be fed back, particularly, from our perspective,
6 to the provider community that needs to use it in the course
7 of constructing meaningful plans for patient health and
8 well-being in the course of integrating both traditional and
9 non-traditional approaches to care.

10 MR. LEVITT: Margaret, just a point on definition.
11 If we can call it AER, and not ADR, then we're ;in the right
12 realm here. If that's fair enough.

13 I think the sources that we have, in terms of
14 spontaneous reporting--the medical literature, the
15 medication error system of USP tests, the toxic exposure
16 surveillance system of the American Association of Poison
17 Controls Centers, NICE out of CPSC--and I may have missed
18 one or two others.

19 As we look at that, and our experience in consumer
20 products, that the sources are there and they are available
21 in terms of bringing in signals. And we've picked up, you
22 know, on a handful of reports on anaphylaxis and a voluntary
23 program for a warning on neosporin, by way of example, and
24 it was only a handful of reports over a fairly long period
25 of time, and therefore very rare reaction. You can get

1 those kinds of signals out of what we currently get, and our
2 experience is that those are--we don't need to look for
3 other sources.

4 I would encourage that you look at our comments--
5 the detailed comments on page 4--as well as what we did last
6 month which the Burton hearings on dietary supplements to
7 get an idea as to where we are coming from, and a broader
8 perspective on AER reporting. And I would also encourage
9 looking at the May '99 report, because it goes to what
10 Lucinda was saying earlier that what needs to happen on the
11 CDER side, as well as the CFSAN side--remember, we're going
12 to have new dietary supplement ingredients come out; we're
13 going to have new drugs that will come out and will be used
14 in a much broader population of people. And the potential
15 for rare interactions in that regard, although they would be
16 rare, and at probably at a low exposure setting, if you
17 will, still need to be tracked. And so we need that
18 integration. And what is outlined in that May '99 report to
19 CDER on medical products I think is the foundational setting
20 for CFSAN to move forward.

21 What we are working on right now is a much more
22 detailed type of plan on AER reporting, in terms of the
23 specifics as to when do you share things, who do you share
24 them with, how are they reported on the Web site? A table
25 of contents as it appears is simply not something that is

1 very helpful and, in fact, potentially misleading, and there
2 may be another way of thinking out of the box on that one to
3 meet the need of being FOI-able, but also meeting the need
4 of being complete, valid and so on. And that's what we're
5 struggling with right now, to get the right kind of thing
6 before August and into the system through our comments.

7 MS. HILDWINE: Again, this is one that we didn't
8 cover in our prepared remarks, but I think it was a year
9 ago--a little more than that--we did present to the Food
10 Advisory Committee relative to safety of dietary supplements
11 on the subject of surveillance.

12 Dietary supplements are foods. We believe the
13 models that have been in place for a long time for foods are
14 very useful here, and those models essentially put the
15 burden for surveillance--the first line of reporting--on the
16 industry, because it is, after all, the industry that's
17 providing products that go into the mouths of consumers.
18 And there is a long history on the food side of FDA-industry
19 cooperation relative to adverse events; a long history of
20 voluntary compliance with the industry; a long history of
21 voluntary recall preparation, which NFPA has been a
22 longstanding part of. We would encourage FDA, keeping in
23 mind that dietary supplements are legally classified as
24 foods, to look to the food models for adverse event
25 reporting and safety surveillance issues in the marketplace,

1 because I think that that's going to be very helpful as you
2 go forward with this process.

3 DR. DICKINSON: We would support this call to look
4 to the food models. We do think the adverse event reporting
5 system has been demonstrably effective in pointing out--
6 signalling--errors, problems that need to be corrected. I
7 think some of the problems that we've had in the ephedra
8 area which is the one, of course, that we're all struggling
9 with most greatly at this moment, comes from trying to over
10 interpret the adverse reaction reports and to draw from that
11 the kinds of information that FDA's own preamble to the
12 adverse reaction list indicates cannot be done: that is,
13 identifying a particular dose that is safe or unsafe;
14 identifying what the denominator is or even, in some cases,
15 what the numerator is. I think the system as it's currently
16 operated has the capacity to work if we apply intelligent
17 analysis to it, as Lucinda was suggesting. And what we're
18 going to be struggling with in our further comments is ways
19 of doing that more effectively.

20 But then you--you know, as in Dr. Levitt's--Mr.
21 Levitt's iceberg that he shows as an example that AERs are
22 really just a signal--just the tip of the iceberg--you
23 really need to go to the underlying science and to other
24 issues, probably, for defining what is a safe dose, and what
25 kind of regulatory action needs to be taken once that signal

1 is sent up.

2 DR. MACKEY: I would simply second Regina's
3 comments. There are certainly examples--published articles
4 in the literature--documenting how adverse events for food
5 additives has been conducted. And, you know, there's some
6 experience there to look into.

7 MR. FORD: I would agree substantially with Dr.
8 Dickinson's comments. I think you need, when looking at
9 dietary supplement, and particularly botanicals, you need a
10 little bit of different criteria as to determine which of
11 these reports make it into your final report as you look
12 through--and as Annette says, you know, this always comes
13 back with--AER seems to come back to ephedra. The reports
14 in there are just all over the place. We have no idea, many
15 times, what the recent history--medical history--of the
16 person is, what else they may have taken, what pre-existing
17 conditions they may have, and that's, I think, important
18 information with botanicals, and I don't know exactly how
19 you always get at that information. I do understand,
20 though, we're talking about a list that has a--as I've said
21 here before--complaint about SlimFast that it had an off
22 taste. Well, you know, so does Drano but I think it would
23 probably produce a much greater adverse event.

24 So there needs to be some criteria about how these
25 reports get in. There was conversation awhile ago among the

1 trade associations and FDA about a consistent 800 number of
2 some kind on the label. That would probably get you more
3 reports, but I'm not sure it would necessarily improve the
4 quality.

5 MR. LEVITT: Thank you very much.

6 Mr. Hubbard?

7 MR. HUBBARD: I actually was going to ask about
8 AERs as well.

9 As you know, with the drug and device model, we
10 rely principally on physicians--the so-called "learned
11 interveners"--and manufacturers for information.

12 Dr. Dickinson, you suggested we could rely more on
13 the manufacturers. Were you thinking of more the drug
14 model, where manufacturers have an obligation to seek out
15 data and report to FDA?

16 DR. DICKINSON: No, I was thinking of a food-based
17 model, but in which the reports, once FDA receives them,
18 would be referred to the manufacturer so that the
19 manufacturer can be involved, both in determining that the
20 actual--the product has been correctly identified; the
21 manufacturer's been correctly identified; provide some
22 additional information to you regarding the ingredients and
23 the nature of the product; and be actively involved in
24 determining the likely association between that report and
25 the product.

1 MR. LEVITT: Bill?

2 DR. SOLLER: Yes, I don't think that a mandatory
3 AER system would necessary be the way to go here, given the
4 overall safety and what we know from the sources of AER
5 reporting. I think we're really talking about refinements
6 to the system.

7 It's true that manufacturers are going to have the
8 sincere motivation of making sure that that AER is as
9 accurate as possible. One of the things that's difficult
10 here is that FDA may not release the name of the voluntary
11 reporter, under MedWatch. And you can understand, it would
12 probably undermine the system. But part of some of the
13 discussions that we've had focus on whether FDA is able to
14 encourage the voluntary reporter to also notify the company,
15 particularly of the serious AERs, because that's what we're
16 really interested in. And I think as you look at the AER
17 system, focus in on the serious ones, recognizing that the
18 broad perspective of all these products is that they're very
19 safe. And if there can be some kind of linkage there, then
20 I think you're able to--linkage between FDA, the voluntary
21 reporter, and then the voluntary reporter also telling the
22 company on the serious AERs--then you're helping to partner,
23 in your follow-up process, by having the company also work
24 in terms of identifying what is a valid report, what may
25 have changed in the report, etcetera.

1 MR. LEVITT: Dr. Yetley?

2 DR. YETLEY: Thank you.

3 Some of you have mentioned the high priority for
4 GMP regulations for dietary supplements. If you were to
5 describe the overarching philosophy that FDA should follow
6 in dealing with GMP regulations, what would it be? And what
7 should it not be--for dietary supplements?

8 MR. FORD: We have approached out GMPs--we believe
9 in the old rising tide lifting all boats. And we have a
10 very inclusive and consultative type of approach. We don't
11 want to intimidate companies. We think that most of them,
12 with a little ratcheting, will do just fine with GMPs. So I
13 think they need to be realistic. But just to cut to the
14 chase, to me the most important elements of our GMPs is that
15 raw material needs to be tested for safety and identity on
16 the loading dock when it's received, and finished product,
17 lots and batches need to be tested for safety and identity
18 as far as label integrity is concerned. And everything else
19 in the middle is important, but that's the heart and soul.
20 Because I think that's the question that keeps getting
21 raised when I pick up the newspaper, is about the safety and
22 identity of the products, and that's what the GMPs, in my
23 view, should be there to guarantee.

24 MR. LEVITT: Let's go down to Annette, and then
25 Bill.

1 DR. DICKINSON: I would agree that the overarching
2 principle for GMPs is to assure that products have the
3 identity and quality that there are represented to have so
4 that consumers have confidence that what they see on the
5 label is what they actually get in the product. And I think
6 that's the direction that the GMP working groups have been
7 going toward as they work through the Food Advisory
8 Committee to refine the proposal that has been discussed.

9 I think one of the things that they are not--at
10 least in our view--is that they are not HACCP; that the
11 nature of this product category is such that GMPs are really
12 the answer to regularizing the products in this category,
13 and that they don't, by and large, represent the kind of
14 microbial or other challenges that have made HACCP FDA's
15 choice in some other product areas.

16 MR. LEVITT: Bill?

17 DR. SOLLER: Yes--generally in agreement. And
18 moving beyond the identity-quality-potency and purity types
19 of goals of GMPs, our experience in GMPs has been that as an
20 overarching philosophy--now, setting that aside from
21 objectives of identity, potency, purity and so on--is that
22 GMPs are best when they specify the goal, and don't over-
23 engineer how to get there. And that is probably the most
24 important overarching philosophy for any product GMP that
25 would fall within FDA's bailiwick.

1 Now, there will be specifics within GMPs, and I
2 don't mean to say that you are totally devoid of those. But
3 it's quite clear that you need to build in the kind of
4 flexibility into GMPs that allow technology advancements,
5 and basically specify: this is your expectation for what
6 identity, quality, potency and purity would be, allowing the
7 flexibility for companies to get there.

8 The second is--and just a brief point--if you had
9 to think about the one area in GMPs that is most sensitive
10 for this industry--and that's the supplier side of this--and
11 ensuring that what comes into the manufacturer, distributor,
12 re-packager and so on is of high quality and known element
13 is extremely important.

14 DR. MAINE: The only other new thought that I
15 would add to that is that they have to be enforceable.
16 That's what the people who are in the distribution channels
17 are--

18 DR. SOLLER Here, here.

19 DR. MAINE: --interested in seeing.

20 MR. LEVITT: Thank you.

21 Just before I move on to Dr. Bowen, I think after
22 we deal with Dr. Bowen's question, I'm going to ask one
23 final one. I'm going to tell you what it is now, so you can
24 also be thinking of it--which is just to go down the panel,
25 rapid fire--looking ahead a year from now--and I'll be

1 asking all the panel this--looking a year ahead from now, if
2 FDA could accomplish one thing in this area, what would it
3 be? So you can be thinking of that as Dr. Bowen asks her
4 question. I don't mean to distract from that, but I didn't
5 want to hit you with that cold.

6 DR. BOWEN: Okay. I think this will be an easier
7 one for you, compared to what you have already been asked,
8 and it's about, again, the safety issue, and the adverse
9 event reporting.

10 I heard that what you want is a prompt and
11 complete notification system, and clearly we also want that;
12 and that what you want is an intelligent system, once we
13 have those AERs reported, in terms of feeding back what we
14 receive. What I'm interested in knowing from you is: does
15 industry, since you prefer a voluntary kind of system--does
16 industry have general SOPs in place that facilitate picking
17 up adverse event reports and would include something like
18 literature reports and screening and surveillance of not
19 only your direct reports but anything else that you could
20 find out?

21 MR. LEVITT: Who would like to start? Dr. Soller?

22 DR. SOLLER: I'm not going to represent that the
23 industry is necessarily consistent across all sectors, but
24 at least my experience is that the larger companies--
25 obviously, those with the resources for the infrastructure--

1 follow AERs as a matter of survival in a litigative world.
2 That's a very clear driving force. And if you then say what
3 about, perhaps, smaller companies, or companies that are
4 starting up and so on, our experience on the OTC side has
5 been as we have had to compile AERs for your Non-
6 Prescription Drug Advisory Committee over these many years,
7 is that we generally can account for the very large exposure
8 of the American public to a particular product. And if
9 you're looking at the inherent toxicity of a particular
10 ingredient, that's what you really need to drive for, as you
11 think about whether it's voluntary or mandatory; that you
12 can really use a system that is able to derive from the
13 large exposure base, but not the entire exposure base
14 necessarily.

15 I'm not sure whether that helps in some of the
16 thinking on where you were going with this--

17 DR. BOWEN: I think that helps somewhat from the
18 OTC drug perspective, and some of the people that are now
19 moving into dietary supplements on that side. But maybe
20 from the food side--the three in the middle--the four, I
21 guess.

22 MS. HILDWINE: The food industry certainly has
23 SOPs in place--most companies do. NFPA helps them--helps
24 set them up. We help educate staff as to what to be looking
25 for. And I would say that operations staff in food company,

1 as well as staff further down the chain, are very vigilant
2 in monitoring problems. A lot of food companies, as you
3 know, have consumer response centers, where they receive all
4 kinds of responses from consumers, including, in some
5 instances, complaints and adverse event reports--at which
6 point science kicks in. Because like all other foods, the
7 adverse events associated with dietary supplements may be
8 somewhat distal to ingestion. And so, at that point, it's
9 very much necessary to determine that the suspect is, in
10 fact, associated with the adverse event. Science does this.
11 NFPA has been doing this for decades to determine that, in
12 fact, an adverse event is associated with the suspect
13 product, at which point companies then--assuming a positive
14 finding--companies then kick into their process to withdraw
15 the product from the market, or engage in a recall, and then
16 if the Agency isn't already involved, involve the Agency.

17 This is--it's very clearly drawn out at NFPA. We
18 have a publication that helps companies set this up, and
19 certainly we'd be happy to make that available to the
20 Agency. I think you probably already have it, as a matter
21 of fact.

22 DR. DICKINSON: If I understood your question to
23 go somewhat beyond, perhaps, what the individual companies
24 may do in the way of SOPs and follow-up, I don't believe
25 there is, on a larger, industry-wide basis, or even on an

1 association basis, the kind of tracking, perhaps, that I'm
2 just hearing that NFPA has in place. And I think this is
3 something we could learn from NFPA's model to do that
4 better.

5 DR. MACKEY: Certainly NutraSweet had an active
6 adverse event reporting process back in the '80s that
7 involved reaction to consumer call-ins. We had physicians
8 on staff to evaluate the claims, get back to the callers
9 personally. This is how some of our studies were--on, for
10 example, whether aspartame caused headaches--this is how
11 some of our studies were initiated; people who claimed that
12 they had an adverse headache after consumer our product.

13 Other companies certainly would do this for fat
14 substitutes as well. We have what we call adverse event
15 reporting. We also have post-marketing surveillance as to
16 how much exposure are getting from our product; is that
17 within the safety that we've established for the product? I
18 think that's another aspect that, in some instances, it
19 makes sense to undertake: just how much are people actually
20 eating, versus what do the data say is the safe level.

21 MR. LEVITT: Thank you.

22 Michael?

23 MR. FORD: Well, I'm not sure I have a lot to add
24 at the end here, but I would agree with the assertion of
25 inconsistency, at least, across the industry. There is sort

1 of an informal system out there that when the distributors
2 come to the health food store every week or two, and if
3 product has been brought back with a complaint, that
4 complaint usually will be voiced by the health food store
5 retailer to the distributor. It gets back to the company,
6 and I think the companies do respond when they see a problem
7 with a product out there; they'll pull the product, or it
8 might affect the way the use directions show up on the
9 label.

10 But it's very inconsistent, and it's quite
11 informal.

12 MR. LEVITT: Okay. Thank you.

13 Well, in the spirit of us all trying to learn
14 something from the meeting today, I hope you'll take back
15 the--certainly--feeling that--the example in the food²
16 industry, there is quite systematic approach that maybe
17 could be looked at by members from industry, too.

18 Okay. My last pop-quiz question: one thing a year
19 from now. Rapid-fire, please.

20 DR. MAINE: Id have to say that it is the--
21 whatever would--it will take to translate credible science
22 related to these products into accessible and meaningful
23 labeling for consumers and health care providers.

24 DR. SOLLER: When I was growing up my dad always
25 asked me "What do you want for your birthday?" and I always

1 said, "Can I have two things?"

2 But number one--drawing from that--and you
3 wouldn't dis my dad, I hope--drawing from that, I would say
4 an enforcement policy that removes unsafe products from the
5 market place and ensures truthful, not misleading, and
6 substantiated claims on dietary supplements. And, secondly,
7 because it will set up what you're going to do for the next
8 three to five years, a strategic plan, or a gaps analysis,
9 that really defines your resource needs.

10 MR. LEVITT: Thank you.

11 Regina?

12 MS. HILDWINE: A lot of what I mentioned had
13 implications for conventional foods, so I'm going to rule
14 all that out, and I'm going to say that a year from now I
15 would really like to see that we've reached the close² of a
16 comment period on a proposed rule on good manufacturing
17 practices for dietary supplements.

18 MR. LEVITT: Thank you.

19 Annette?

20 DR. DICKINSON: I would endorse the GMP as one of
21 those but, like Bill, I'm going to take the opportunity to
22 have a second one, and the second one is a visible FDA
23 presence, in terms of implementation and enforcement, so
24 that we deal with the outliers, and so that the impression
25 is not given that there's a vacuum.

1 MR. LEVITT: Thank you.

2 Maureen?

3 DR. MACKEY: Yes, I would say that there were
4 consistently applied standards; guidance from the Agency as
5 to how to do that; how to affirm the safety of your product
6 and to substantiate it's claims.

7 MR. LEVITT: Michael?

8 MR. FORD: I want to read in the Washington Post:
9 "Year-long FDA Moratorium on DSHEA Regulation Promulgation
10 Works." The bill--" 'The Act is a good one when we enforce
11 it,' Levitt says."

12 [Laughter.]

13 MR. LEVITT: Okay. Very good.

14 Listen, I want to thank this panel very much. And
15 if we can, I guess, in an orderly way--I wasn't here when
16 you--I don't know what you had to do to get up here--

17 [Laughter.]

18 --but if we could exit that way and allow you to
19 get off before the next group tries to come up. But our
20 next group is composed of Paul Thomas, Tracy Fox, Mary Ellen
21 Camire, Joseph Valentino.

22 [Pause.]

23 MR. LEVITT: Okay. While we are on logistics--I
24 mean, while we're moving back and forth, let me do a couple
25 of logistical things. I will repeat this just before lunch,

1 but in case anybody wants to leave before I get to say this-
2 -attendees who are not government employees, which, looking
3 around the room, is most of the people in the audience, who
4 did not get visitor's passes when you went to the building,
5 if you want to get back in after lunch you need to pick up a
6 pass from the staff on your way out from lunch. There are
7 going to be only just the correct number of passes for the
8 non-government folks who signed in with the guards. So if
9 you want to get back in, you need to get your guest pass so
10 when you come back in it's an easier process. I will repeat
11 that later. But it certainly did serve a purpose, and allow
12 our next group of speakers to be seated. So I'll get a two-
13 fer out of that.

14 Thank you. I suspect most of you were here at the
15 beginning but, if not, we'll ask to go five minutes per
16 speaker. We have somebody sitting right up here that will
17 give you a one-minute warning and final, friendly "Time is
18 up;" and ask speakers to adhere to that as much as possible.

19 Then we'll go down the list. Each of us will ask
20 one question, and then afterwards I give you a chance--the
21 "year from now" question, or what do you want from your
22 birthday a year from now, to use the Sollerism.

23 Okay. With that, our first speaker is Paul
24 Thomas, Secretary of SNE.

25 **PANEL II - NUTRITION PROFESSIONALS; FOOD INDUSTRY**

1 DR. THOMAS: Okay. Well, thank you and good
2 morning.

3 The 1,400 members of SNE acknowledge the growing
4 role that supplements play in American life. We also
5 recognize the need for more authoritative information about
6 them so consumers can make more informed, sensible decisions
7 about supplement use. But we think that making such
8 decisions can be hard in today's environment. It's only
9 natural that so many people are confused about supplements,
10 given the large number of products available and the
11 plethora of information from advertising, product
12 promotions, media reporting of single studies, and word-of-
13 mouth from sellers. It's hard even for experts to separate
14 from the pseudo-science without a good bit of digging.

15 SNE recommends that FDA consider adding a strong
16 consumer research and information component to its overall
17 strategy on regulating supplements, and we have three
18 specific suggestions.

19 Number one, FDA should take the lead in conducting
20 and encouraging others to conduct high quality consumer
21 research on supplement use. Last year, FDA asked its Food
22 Advisory Committee to help identify questions to ask
23 consumers about supplements in future surveys and focus
24 groups. FDA's Alan Levy stated that while half the
25 population takes supplements, very little is known about

1 consumer understanding and use of product labeling. He
2 added that FDA's current research on supplements focuses on
3 who uses them, how many are used and reasons for use, in a
4 relatively simple kind of way: "What do you take? What are
5 you using it for?" "I take echinacea for colds." "Thank
6 you." Dr. Levy acknowledged that more research is needed
7 where consumers are asked their thoughts about supplements.

8 Now, we agree. Clearly more research is needed on
9 how the labeling, advertising and various promotions of
10 supplements shapes consumer perceptions of them and their
11 willingness to try such products. We need detailed studies,
12 both qualitative and quantitative, and theory-based, that
13 explore how consumers come to decision about whether or not
14 to supplement, and details of the decision-making process
15 itself. Do consumers make meaningful distinctions between
16 health claims and nutritional support claims? Do they
17 evaluate advertising copy and label information in the same
18 way or differently? What do consumers recommend that FDA do
19 to regulate supplements? The research needs to move beyond
20 simple surveys and a few focus groups.

21 FDA might use its Food Advisory Committee to help
22 define the questions that need to be asked, and do what it
23 can to stimulate the needed research. FDA might also
24 develop a workshop or conference to get advice from the
25 scientific community on developing a more consumer-focused

1 research agenda on supplements, and we can, of course,
2 provide you the names of some Society for Nutrition
3 Education members who might want to participate.

4 Now, suggestion two. At present, supplement
5 manufacturers do not have to provide FDA with substantiation
6 of their claims of nutritional support for their products,
7 even though DSHEA says the manufacturer must have that
8 substantiation that the claims are truthful and not
9 misleading. We believe that FDA should require that the
10 evidence on which the manufacturer is relying be provided to
11 the agency and be made publicly available. Then more claims
12 of nutritional support might be investigated by scientists,
13 journalists and perhaps even FDA itself. The results, we
14 think, would help consumers become more savvy users of
15 supplements.

16 Suggestion three. Consumers and health care
17 professionals need easily accessible and authoritative
18 information about supplements without having to search too
19 many diverse sources, or to conduct their own literature
20 reviews. The Office of Dietary Supplements, for example, is
21 preparing fact sheets on some supplements. U.S.
22 Pharmacopoeia has produced short monographs on various
23 botanicals. And recently, the American Society of
24 Anesthesiologists issued a warning about using certain herbs
25 before surgery. Authoritative information such as this

1 should be accessible from a single source that is very
2 frequently updated. The FDA or ODS Web site might be the
3 right source. But irrespective of placement, FDA could do
4 more to encourage the development of a central source of
5 authoritative statements regarding supplements, and then
6 promoting it.

7 And, again, on behalf of the Society for Nutrition
8 Education, I want to thank you for the opportunity to
9 comment on FDA's efforts to develop an overall strategy for
10 regulating supplements. Consumers need easy access to good,
11 authoritative information to make sensible decisions about
12 these products and more consumer research is needed to
13 develop better policies and regulations that will allow the
14 dietary supplements industry to thrive, but not at the
15 expense of consumer misunderstanding and confusing about the
16 benefits and limitations of its products.

17 Thank you.

18 MR. LEVITT: Thank you very much.

19 Our next speaker is Tracy Fox, American Dietetic
20 Association.

21 MS. FOX: Good morning. My name is Tracy Fox.
22 I'm a registered dietitian and a senior Federal regulatory
23 manager with the Government Affairs Office of the American
24 Dietetic Association.

25 With over 70,000 members, ADA's mission is to

1 serve the public through the promotion of optimal nutrition
2 health and well-being. ADA supports the need for consumers
3 to have access to dietary supplements as long as their
4 opportunity to choose is made in the context of a fully
5 informed choice and assured public safety measures. To this
6 end, we continue to stand behind the need for stricter
7 regulation and oversight of the dietary supplements, and
8 applaud the efforts of FDA.

9 We congratulate FDA for holding this open meeting
10 and soliciting input from various organizations on the
11 complex issues surrounding the regulation of dietary
12 supplements. We also urge FDA to look closely at the
13 recommendations made by the Presidential Commission on
14 Dietary Supplement Labels in November of 1997 to ensure that
15 these recommendations are incorporated effectively into
16 FDA's overall strategy.

17 In my oral testimony today, I'll highlight some of
18 the key issues that ADA urges FDA to consider as you proceed
19 through developing a strategy. My written comments provide
20 much more detail in a number of areas, including adverse
21 event reporting, good manufacturing practices, and
22 significant scientific agreement. Copies of the testimony
23 are out front as well.

24 FDA has asked whether there are other objectives
25 in addition to ensuring consumer's access to safe dietary

1 supplements that are truthful and not misleadingly labeled
2 that should be addressed in an overall dietary supplement
3 strategy. Frankly, if FDA accomplishes this and this alone,
4 given the relative limited authority it has under DSHEA,
5 then the strategy should be considered an enormous success.
6 However, ADA recommends that that statement--"ensuring
7 consumer access to safe dietary supplements that are
8 truthful and not misleadingly labeled"--should be the
9 overarching goal of FDA's supplement strategy. This goal
10 would then drive the development of more specific and
11 measurable objectives to coincide with elements of the
12 Center for Food Safety and Applied Nutrition--the elements
13 that they have already identified in the 1999 program
14 priorities document--as well as the recommendations that
15 were made by the Presidential Commission on Dietary
16 Supplement Labels. We also urge FDA to consider
17 establishing an advisory committee on dietary supplement
18 comprised of multi-disciplinary, well-respected experts to
19 provide on-going counsel and guidance.

20 ADA agrees with the need to define boundaries
21 between the various categories of products in order to
22 provide industry with a more structured approach to
23 marketing and labeling, and to provide consumers with
24 accurate information. The proliferation of claims on a
25 variety of products has created an environment of confusion

1 and distrust among health professionals and consumers.

2 Within the dietary supplement definition, we urge
3 FDA to consider an approach that delineates those
4 supplements that occur naturally in commonly eaten foods,
5 and those that do not. Under this approach, vitamins and
6 minerals for which some form of requirements or formulation
7 standards have been established, such as by the Institute of
8 Medicine, or United States Pharmacopoeia, and about which
9 there is a considerable research base, would be in one
10 category along with other known nutrients or components of
11 body function. Botanicals, like St. John's wort, echinacea,
12 as well as hormones, like DHEA and melatonin, of which less
13 is known, and therefore present unknown or potentially
14 greater risk, would be in a different category. The
15 components in the latter category would require more
16 scrutiny or limits. This would also help the Center in
17 allocating resources and focusing on supplements that could
18 present a greater risk.

19 ADA continues to believe that health and nutrient
20 content claims, as well as structure and function claims on
21 foods and dietary supplement should be based on the totality
22 of publicly available scientific evidence, including results
23 from well-designed studies conducted in a manner that is
24 consistent with generally recognized scientific procedures
25 and principles. DSHEA, as well as the 1997 Food and Drug

1 Administration Modernization Act, did not change that
2 overarching public health need. To this end, we urge FDA to
3 expeditiously outline criteria on characteristics for
4 significant scientific agreement. This will help the
5 public, consumers, researchers and certainly the industry
6 itself. And my written comments go into much more detail
7 about the components of significant scientific agreement and
8 some ideas.

9 ADA, like the Society for Nutrition Education,
10 supports the need for the contents of manufacturers'
11 substantiation files to be more readily available--to FDA as
12 well as health professionals, researchers and consumers.
13 How can consumers make informed choices, or health care
14 professionals be knowledgeable about products, if the only
15 information available is what's contained on the supplement
16 label--equivalent in size to a 3x5 inch index card. In
17 addition, when claims are made for supplements and the
18 research base includes a particular formulation, then the
19 product making the claim must use the same formulation.
20 That's common sense.

21 I see my time is up. I think some of the other
22 areas, including communicating to consumers as well as
23 research needs and the research area, we would certainly
24 support more research into basic supplement research itself,
25 in terms of the bioactive components and the mechanisms

1 underlying the action of the supplement. We also support
2 the need for additional consumer research. We need to
3 understand their attitudes, purchase decisions, usage
4 behaviors, and sources for dietary supplement information.

5 Again, thank you for the opportunity of allowing
6 ADA to testify, and we certainly urge FDA, as they struggle
7 with developing a strategy, to think of consumers first and
8 foremost in implementing a strategy and, again, to take a
9 look at the recommendations by the Presidential Commission.
10 And we look forward to working with FDA, other government
11 agencies, the private industry--food industry, supplement
12 industry--in reaching the ultimate goal of providing safe
13 supplements to consumers.

14 Thank you.

15 MR. LEVITT: Okay. Thank you very much.

16 Our third speaker on this panel is Dr. Mary Ellen
17 Camire, IFT--Institute of Food Technologists.

18 DR. CAMIRE: I'm Mary Ellen Camire, and I'm an
19 associate professor in the Department of Food Science and
20 Human Nutrition at the University of Maine, and I'm speaking
21 here on behalf of the Institute of Food Technologists, which
22 is a non-profit scientific society with about 28,000 members
23 working as food scientists, food technologists and in
24 related professions, in academia, industry and government
25 positions. We will be submitting written comments later in

1 more detail; particularly academicians like myself like to
2 take a little break in the summer. But we'd like to make
3 three main points today.

4 We think that some clarifications that will be key
5 to FDA's overall strategy will be making clear distinctions
6 between foods and dietary supplements. There is a great
7 deal of confusion I think, both for manufacturers and
8 consumers at this time. You can walk into stores and see
9 soups and teas that are clearly marked "Herbal Supplement"
10 on their front package panel. They contain a supplement
11 facts panel containing nutrition information. Is this
12 enough information for consumers to know if it's a food or a
13 supplement, when it looks and it appears in every other
14 respect like a food. It's not clear. And this is what the
15 consumer research will be very important.

16 Many food products, and particularly we're seeing
17 this in snack foods and beverages, are adding botanicals and
18 other dietary supplement ingredients to conventional foods,
19 but maintaining that food identity, keeping the nutrition
20 facts panel. So you may have a tea which is a very
21 traditional way of taking botanical ingredient, but add St.
22 John's wort or another herb, and then it's up to the
23 manufacturer to decide are they inclined to market it as a
24 dietary supplement or as a food. In some cases the
25 packaging is the only distinction that the ingredients may

1 be exactly the same. And I think that's very confusing to
2 people, particularly small food manufacturers like we have
3 in Maine.

4 In order to prevent unnecessary research and
5 development expenditures which may be exceeding possibly
6 millions of dollars at this point for food products that
7 contain added dietary supplement ingredients, it would be
8 very helpful for FDA to issue a talk paper or similar
9 vehicle to explain to food manufacturer how these
10 ingredients can be incorporated, and what the distinctions
11 between foods and dietary supplements are.

12 The second issue we'd like to address is to urge
13 FDA to assign priority to finishing up unfinished business;
14 that final rules or to let people know rules will be issued
15 on issues that have come up in the past and need to be taken
16 care of. In particular, the advance notice of proposed
17 rule-making for ephedra-containing supplements was issued
18 over two years ago, and IFT strongly made comments over four
19 years ago regarding the safety of ephedra supplements.

20 In addition to working on that one, which I think
21 is important in terms of preventing any additional deaths,
22 while maintaining access for the people who are using these
23 supplements responsibility and do use it in the traditional
24 fashion, we also need to make sure that there's rules coming
25 out--forthcoming--on good manufacturing practices and though

1 we don't totally agree maybe with some of the proposed ideas
2 regarding structure/function claims and the definition of
3 disease, that closure needs to be brought to that subject as
4 well.

5 Finally, we'd like to recommend formation of
6 dietary supplement advisory committee, though I'm going to
7 amend my remarks, given the discussion we've had this
8 morning that some form of advisory group is needed, maybe
9 not in the traditional sense; scientists with expertise in
10 botanicals, particular, but also other dietary supplement
11 ingredients, could provide very important and valuable
12 assistance to FDA in what has become a great deal of
13 research burden for FDA scientists. The Food Advisory
14 Committee thus far has done an excellent job working with ad
15 hoc groups, but we think additional assistance is needed,
16 and this may help reduce some of the workload involved with
17 dietary supplements. And although the formation of such a
18 committee was not outlined in the CFSAN priorities, I think
19 perhaps it should be added.

20 Thanks.

21 MR. LEVITT: Thank you very much.

22 Our final speaker on this panel is from the USP,
23 Joseph Valentino.

24 MR. VALENTINO: Thank you for this opportunity.

25 The United States Pharmacopoeia is a unique

1 organization. We're a non-profit standard-setting body, and
2 we publish the USP--the United States Pharmacopoeia National
3 Formulary--and these are the only non-governmental
4 pharmacopoeia in the world. It's because of this uniqueness
5 that I never know where we're going to be placed on a panel.
6 So today, I guess, either I'm a nutritional professional or
7 a member of the food industry.

8 Because of time constraints, I'll address the
9 questions posed in the Federal Register in our written, but
10 I'll try to use my time today to focus on a specific area
11 that we believe needs attention by the Agency.

12 The United States Pharmacopoeia promotes the
13 public health by establishing and disseminating officially-
14 recognized standards of quality for the use of medicines and
15 other health care technologies. In 1995, based on concerns
16 about the safety, quality and use of dietary supplements,
17 USP members--about 400 organizations--adopted a resolution
18 to provide standards for these products. Over the past four
19 years USP has begun developing monographs in the National
20 Formulary for those botanical-based dietary supplements that
21 account for about 90 percent of U.S. retail sales. This is
22 approximately 24 botanicals, and I have a chart in my
23 handout which indicates the status of the progress we've
24 made.

25 These monographs contain standards of identity,

1 strength, quality and purity, and there's even a chapter on
2 manufacturing practices for nutritional supplements.
3 Compliance with standards in the official compendia the USP
4 and NF would help eliminate the reported problems involving
5 potency variations and product contaminations.

6 The Federal Food, Drug and Cosmetic Act indicates
7 that dietary supplements purporting to conform to the
8 standards of the official compendia must do so, or they will
9 be considered misbranded. FDA should take regulatory action
10 against those products which purport to meet USP or NF
11 standards on their label and that fail to do so. Further,
12 the FDA should take advantage of this provision regarding
13 dietary supplements and the USP-NF recognition in the drug
14 provisions of the Food and Drug Act, by recognizing USP
15 standards and NF standards and methods of analysis in their
16 regulations, and encourage their use by industry to ensure
17 the potency and purity and ultimately the safety of dietary
18 supplements. We would also welcome the participation in the
19 development of these standards and analytical methods by
20 FDA.

21 Compliance with USP or NF standards would provide
22 for uniform designations of identity and strength on labels,
23 and would allow consumers to make meaningful selections of
24 products and be assured of their performance.

25 Now, in order that consumers not be misled, USP

1 recommends that FDA also carefully review labeling that
2 inaccurately implies compliance with USP or NF standards, or
3 contains statements that are false or meaningless, or
4 designed to mislead consumers as to the quality of the
5 product. Included among these statements are--quote--
6 "standardized" or "meets laboratory standards," or some that
7 even say "meet USP dissolution standards." The first two
8 statements do not provide useful information to consumers.
9 And even the third may be misleading if the product is not
10 in the USP or NF; or, if it is, and it meets the USP
11 dissolution standards but it fails to meet the other quality
12 standards.

13 In conclusion, let me say that USP looks forward
14 to working with the FDA to assure the quality of dietary
15 supplements in the marketplace.

16 MR. LEVITT: Thank you very much.

17 Again, we'll go through the same process we did
18 before. I'll start with a question and we'll proceed right
19 down the row.

20 My question is on the issue of substantiation of
21 claims. A couple of speakers addressed that to some degree,
22 and my question is where would you put, in an overall
23 priority, the substantiation issue on claims, compared to
24 some of the safety issues that have gotten also a lot of
25 comment already today--primarily the enforcement; the AERs,

1 the GMPs and so forth. I think everybody agrees
2 substantiation is needed, but where do you think that fits
3 in the hierarchy, in terms of urgency?

4 Please?

5 DR. CAMIRE: Well, I think we have to maintain
6 safety as the number one priority, but substantiation is
7 important, particularly given the NPR survey that came out
8 this year that said more than half of Americans surveyed
9 didn't feel that the claims that were on dietary supplement
10 labels were really accurate, to paraphrase them.

11 So I think that's important to consumers that hey
12 have some confidence in what's on the label. But I think we
13 don't have the framework yet to be able to make those
14 recommendations and that may be a longer-term goal; within
15 the next three to five years.

16 MR. LEVITT: Good. Thank you.

17 Tracy?

18 MS. FOX: Again, I would have to agree--we can't
19 say safety is going to be second, and substantiation first.
20 However, I do think that substantiation is absolutely
21 critical. If there can be two top goals it would be safety,
22 clearly, and substantiation. Because if FDA is going to
23 adhere to the strategy of making sure that consumers are not
24 misled, then that is substantiation, and that is also
25 safety. And I think that is absolutely critical.

1 There are many claims out there, on many different
2 types of products, and I think we need to rein that in and
3 really get a feel, as health professionals, what we can be
4 telling consumers.

5 MR. LEVITT: Thank you.

6 Anybody else want to address--it's optional.

7 MR. VALENTINO: I was just going to say that I'll
8 limit my remarks to the standards aspects, and I think that
9 the--it's important that the claims being made regarding the
10 standards and the quality of the product be substantiated,
11 and that FDA take a separate look at that.

12 DR. THOMAS: And I would just concur, as well,
13 that safety probably first, but substantiation of claims is
14 a very close second. And, let's face it, consumers are
15 deciding whether or not to take particular supplements
16 largely on the basis of hoping for some kind of effect. And
17 what is on the label is probably--and also in advertising--
18 is probably a major source of information for them in their
19 decision-making process. And, unlike with foods that you
20 might eat because they taste good, they're crunchy--you
21 know, that sort of thing--you're taking dietary supplements
22 for specific health-related types of effects, and here the
23 labeling and the information that is available about them is
24 critical.

25 MR. LEVITT: Okay. Thank you very much.

1 If I could pass the microphone over to Margaret
2 Porter.

3 DR. PORTER: My question is a follow-up to
4 something that I think I heard Tracy Fox say, which is
5 suggesting in that as we tray--the Agency tries to figure
6 out how to set priorities, that we may want to consider
7 looking at the universe of dietary supplements and drawing
8 distinctions among the categories. And I think I understood
9 you to say that with respect to dietary supplements that
10 might be naturally occurring in commonly eaten foods,
11 perhaps we ought to consider giving a lower priority, or a
12 lower attention to those products; and that with respect to
13 botanicals and hormones, that we might apply a higher
14 scrutiny. And I was wondering if I heard you right and, if
15 so, if you might elaborate on the basis for that
16 recommendation, and also what the other panelists might care
17 to comment.

18 MS. FOX: You did hear me correctly, in terms of--
19 within the definition of dietary supplement as FDA
20 undertakes the very difficult task of defining the
21 boundaries, I think because we all recognize there are
22 limited resources. We also all recognize that there are
23 very safe products out there, and very--with a very good
24 research base. And I think you need to draw the line
25 somewhere. This is just a consideration. It's clearly very

1 preliminary; it's something that as we were struggling with
2 trying to identify, within our own minds, the boundaries and
3 the definitions, that this is one approach that I think is
4 worthy of further discussion; not necessarily drawing the
5 line very clearly. I don't think that's going to happen.
6 But I think it's at least a gradation approach, in terms of
7 trying to identify those products that we really don't know
8 much about but for which--are out there in the marketplace,
9 consumers are purchasing them and taking them, and we don't
10 have a strong research base for them.

11 So that is one approach that I think is worthy of
12 consideration and further discussion.

13 DR. PORTER: Is there anybody else who's
14 interested in commenting on that?

15 DR. CAMIRE: I'd just like to say that in regards
16 to the research priorities, I think it ties in that this is
17 an area we need more research, and I agree that we have a
18 little bit more comfort level with things that are derived
19 from foods and culinary herbs, but we're not sure how
20 processing many of these components: when we do an alcohol
21 extract, when we freeze-dry, when we isolate individual
22 components. And we don't know how that effects the efficacy
23 and the safety of those isolated materials. And that
24 certainly could be something for CFSAN to consider as a
25 research area.

1 MR. VALENTINO: I was going to say, from our
2 perspective, we--obviously, if there's an inherent
3 toxicology problem with a substance we'll try and set
4 standards for it. But we say items are "safe." They're
5 safe if what we think they are. But if you can have
6 something with not an inherent adverse effect but yet if
7 it's contaminated with pesticides or some other impurity, or
8 it's transformed somehow, that article is no longer safe.
9 So what we have done is we've given priority to attempting
10 to cover as many products on the market--the largest
11 percentage on the market that the people will be taking--
12 with this in mind.

13 DR. THOMAS: And I would agree with both Tracy's
14 recommended protocol and Joe's statement, as well, that you
15 take into account the--perhaps the naturalness, the
16 familiarity of the different types of supplements as a set
17 of criteria, but also, probably, as important, is the number
18 of people that are taking particular kinds of supplement, as
19 perhaps measured by sales volume is one measure.

20 MR. LEVITT: Okay. Thank you very much.

21 Bill Hubbard.

22 MR. HUBBARD: As you know, one of the provisions
23 of DSHEA differentiated so-called structure/function claims
24 from disease claims.

25 The earlier panel was fairly critical of the

1 proposal we did on that issue recently, but yet they were
2 also urging us to act against unsubstantiated claims.

3 Do you have any views on that proposal? The
4 structure/function proposal? Are you familiar with it?

5 MS. FOX: Yes.

6 DR. THOMAS: Well, I--I'm sorry.

7 MS. FOX: Go ahead.

8 DR. THOMAS: I'm familiar with it personally, but
9 as far as the Society for Nutrition Education goes, probably
10 most of its members and its Board has not evaluated it, so I
11 wouldn't be comfortable in speaking for them on that
12 particular proposal.

13 MS. FOX: ADA did provide comments on the proposed
14 structure/function claim rule, and I believe we--I think we
15 generally support the definition that FDA proposed of
16 disease. And, certainly, while we agree with the need for
17 guidance in the area of structure/function claims, I think
18 that is one of the most difficult undertakings in terms of
19 trying to really grapple with the complex issue of what is a
20 structure/function claim and what is a disease claim. And I
21 frankly think that that's where the consumer research is
22 needed, because I don't think consumers really know the
23 difference between--or really--not that they don't know the
24 difference between it, but I really think they can easily
25 extrapolate from the structure/function claim to--perhaps

1 inappropriately, to a disease claim. And I think the
2 consumer research base is probably going to need to be there
3 much more strongly in order to really handle that issue
4 effectively.

5 Any other reactions to that?

6 Okay. Dr. Yetley?

7 DR. YETLEY: Either explicit or implicit in many
8 of your comments was the need for research and sound science
9 to back up a lot of the issues. You're all members of
10 professional associations. What ways can your associations
11 help us leverage research expertise and actual funding for
12 research projects?

13 DR. CAMIRE: Well, I'll address that, since I'm
14 incoming chair of IFT's research committee and nutrition
15 division.

16 I think that IFT, in particular, because we have
17 people working in the food industry, in the dietary
18 supplement industry, and food scientists as well as
19 nutritionists, we'd be happy to provide expertise and to
20 help point out individuals who may have expertise that FDA
21 does not have. I think it's also important for us to make
22 sure that you have adequate funding, and I think the last
23 panel addressed the need for FDA to tell us what you're
24 going to need in order for us to help get funding so that
25 you're able to adequately do your research.

1 MR. VALENTINO: In April of next year the USP
2 convention will be meeting, and they will be electing an
3 expert committee on dietary supplements. And it may be that
4 we should explore ways on how the FDA can utilize and get
5 opinions or decisions or whatever from this expert committee
6 more than they do now. Right now you have an ad hoc
7 reviewer that sits in at the meetings and learns from their
8 deliberations, but there may be something more formal that
9 we can do with the Agency so that you can take advantage of
10 this expert group.

11 MS. FOX: I think also as FDA establishes kind of
12 its research agenda in terms of the types of research
13 needed, it would be beneficial to establish, or to really
14 closely look with industry, with scientists, with
15 researchers, to look at creative funding mechanisms as well;
16 funding mechanisms that can take advantage of, I think, the
17 experts and the resources in the industry arena, and tap
18 into that to focus research, as well as develop strategies,
19 that it can be very complementary in terms of being as
20 objective as possible, yet still tapping into the resources
21 and the expertise of the industry.

22 MR. LEVITT: Okay. Very good.

23 Dr. Bowen.

24 DR. BOWEN: Okay. This is a somewhat more
25 directed question about research.

1 Three out of four of you mentioned consumer
2 research should be an FDA priority. And I'd like for you to
3 comment--each of you--on FDA's role, what that should be.
4 Should it be to encourage the research? To ask for it? To
5 actually do the research? And, in your opinion, what do we
6 need to know from consumers?

7 DR. THOMAS: Well, I think I presented some of
8 those research needs in my statement, but I certainly think
9 that FDA needs this kind of research; at the very least,
10 should be asking for it; certainly should be encouraging it;
11 and, to the extent that it can, given its limited resources,
12 actually undertaking it. And, certainly, under Alan Levy,
13 you have made some good moves in that direction and have
14 raised some interesting issues with the focus groups and
15 questions that prompt additional kinds of questions and
16 research needs.

17 I think we need more knowledge of consumer
18 behavior regarding supplements in terms of the sources of
19 information that they use; their evaluations of labeling
20 information and advertising claims, and how that affects
21 their decision-making process--their general sense of the
22 potential usefulness of dietary supplements.

23 I also think it's probably a good idea that more
24 effort be made, actually, to find out what consumers think
25 FDA's role should be in the area of dietary supplements and

1 its regulation. And probably this isn't for FDA alone, but
2 also for consumer input related to decisions regarding
3 policies within the Federal government as a whole, including
4 Federal Trade Commission, for example. And I think this '
5 kind of information is really very critical for FDA and
6 other agencies to develop effective public policies in this
7 area that respond to perceived consumer needs, and that are
8 likely then to be better liked and appreciated because of
9 having had the opportunity of input rather than what is
10 often, typically, the case, where we have a variety of, you
11 know, industry, professional societies, etcetera--the usual
12 group of people that generally comment in forums such as
13 this and to proposed regulations. They need to be asked
14 more directly.

15 MR. VALENTINO: I was going to say that the USP
16 just recently conducted a study as to what is considered
17 "useful information" for patients, relative to the patient
18 inserts for medications. And this was done in conjunction
19 with Duke in North Carolina. And it may be that we could
20 develop another program which could tack onto that, and
21 would be considered useful information relative to dietary
22 supplements.

23 MS. FOX: I think also there--since the use of
24 dietary supplements is growing so rapidly, some of the
25 government survey instruments have also been modified, or I

1 know there are plans for modifying some of those large-scale
2 instruments to capture this important information from
3 consumers. And I think efforts in that direction should be
4 increase as well. There might be some opportunities with
5 CDC behavior factor assessment survey. There might be some
6 really good opportunities to, across the board, capture some
7 very basic information, even just on usage; how consumers--
8 what they view the label as, in terms of dosing
9 requirements.

10 There was a recent article in the Journal of the
11 American Dietetic Association that found the majority of
12 high school students exceeding dosage on a very regular
13 basis for supplements, of course, that were recommended by
14 their coaches. And I think this is the kind of information
15 that we really need, and we need more of. And I think there
16 are some opportunities in existing survey instruments. UPS
17 does one. ADA does a trend survey. These are really good
18 avenues to take a look at, as well as government surveys.

19 DR. CAMIRE: And I'd like to echo Tracy comment
20 that I think it's important to encourage collaboration on
21 this issue. USDA and ODS, CDC; FTC has done some excellent
22 work in this area--their study on how consumers responded to
23 qualified health claims and advertising. It could very
24 easily be reworked into looking at structure/function claims
25 on dietary supplements.

1 But I think it would be also important to look at
2 how consumers respond to that disclaimer, and to see if that
3 is really helpful or not, because that does take up, you
4 know, valuable space on the package label, and to find out
5 really--my personal sense is that people disregard the
6 disclaimer and they are, indeed, using the supplements to
7 treat or prevent a disease. And if, in fact, that is how
8 the public is using them, then we may need to re-think about
9 how we provide these claims on the package labels.

10 DR. BOWEN: Thank you. I think those suggestions
11 are very helpful.

12 MR. LEVITT: For our one last final question--you
13 heard before--a year from now, if there was one thing that
14 could be accomplished, that would be?

15 Dr. Thomas--we'll move right down the row.

16 DR. THOMAS: Well, again I think that we will have
17 significantly more knowledge of consumer behavior regarding
18 supplements, and maybe a workshop or a conference with a
19 broad group of people to help set a research agenda.

20 MR. LEVITT: Mr. Valentino?

21 MR. VALENTINO?: I think I'd like to see a joint
22 USP-FDA committee formed, and that they be charged with
23 three things: one, that we develop an active working
24 relationship in the standards area, where you comment and we
25 develop standards, not only for the materials but for the

1 extracts, and for the dosage forms, and the development of
2 reference standards. That's very important in this area.

3 Two, I think the committee should be charged with
4 exploring with USP cooperating with our practitioners
5 reporting programs. We do operate practitioner reporting
6 programs in which we make information available to the FDA
7 and the industry now, and we may be able to work off of
8 these programs and cooperate with you on that.

9 And then the last point was the one I made
10 previously. I think that they'd be charged with exploring
11 how the FDA could utilize the decisions of the USP advisory
12 panels in their decision-making.

13 MR. LEVITT: Thank you.

14 Tracy?

15 MS. FOX: To not have to testify at any more FDA
16 hearings--

17 [Laughter.]

18 MS. FOX: --on this issue, because it's all been
19 resolved.

20 Actually, I think probably the two main areas are--
21 -I'd have to say safety first, to make sure that the system
22 in place in this country provides assurances to health care
23 professionals and consumers--and I think it's important to
24 say "provides assurances," because I believe for the most
25 part the system is safe, in terms of the manufacturing of

1 supplements, but I think more importantly, consumers need to
2 feel comfortable, and so do health care professionals.

3 And I think the next phase would be claims
4 substantiation. I think that's a critical first step in
5 educating consumers, and educating health care professionals
6 on the effective, ineffective, appropriate, inappropriate
7 uses of supplements.

8 MR. LEVITT: Thanks.

9 And Mary Ellen.

10 DR. CAMIRE: I'd obviously like to see final rules
11 on the ephedrine-containing supplements, and I'd also like
12 to see more supplement companies feeling comfortable putting
13 contraindications on their product labels.

14 MR. LEVITT: Okay. Thank you very much.

15 Before I let you go down, let me just take a
16 couple minutes on logistics.

17 First, not to scare anybody, but we're on
18 schedule.

19 [Laughter.]

20 Before people leave, there are three quick
21 announcements that I need to make. One is, as I said
22 before, if you're not a government employee, and you did not
23 get a visitor pass, on the way out, if you want to get back
24 in easily, please get a visitor pass on your way out.
25 That's number one.

1 Number two is that in your package you do have a
2 green sheet that looks like this, that lists some convenient
3 places for lunch that you can get to and back in an hour.

4 And, number three--and I'll repeat this again
5 after lunch, but in case there's some people that are not
6 coming back--with regard to the meeting in July in
7 California, we had provided a contact in the Federal
8 Register: our public affairs specialist, named Janet
9 McDonal, and we had provided a phone number and a FAX
10 number. Under Murphy's law, some people have had trouble
11 getting through on the phone and/or the FAX, and I would
12 like to provide, in addition, an e-mail contact, which is
13 JMcDonal--without the D at the end, for some reason--so
14 that's JMcDonal@ORA.FDA.gov. Again, that's
15 JMcDonal@ORA.FDA.gov for interest in the California meeting.
16 And again what we're hoping is we'll get different speakers.
17 The goal is not to see if the same speakers can fly out to
18 California and repeat the same presentations.

19 [Laughter.]

20 MR. LEVITT: No word that Tracy will do that--but
21 we're hoping to get a different mix of people so they didn't
22 have to fly east.

23 My watch, it says that it is 12:20, so we will
24 begin--try to begin promptly at 1:20 back in this room.

25 I thank you very much. Thank you to the speakers.

1 And, Tracy, thank you especially for coming back twice in a
2 month.

3 [Luncheon recess.]

4 MR. LEVITT: It being 1:20, we are able to get
5 going. I actually looked around and said, "Oh, we can't
6 start yet, the next panel isn't up there." I just hadn't
7 invited them up yet.

8 So, again, for those that were not here this
9 morning, my name is Joe Levitt. I'm Director of the Center
10 for Food Safety and Applied Nutrition, and we are part way
11 through out open public meeting on looking at an overall
12 framework for the regulation of dietary supplements.

13 I have a couple of announcement's that I'll either
14 repeat or make for the first time, while we have everybody
15 back and attention.

16 Number one, at the end of the day--at the end of
17 the day, we will provide some time for members of the public
18 who did not have an opportunity to schedule time in advance--
19 -if you want to speak, we ask you to sign up outside at the
20 registration desk. We do have a couple of people that have
21 signed up. We would try to limit these presentations to
22 about three minutes each, as the hour will be late by then
23 but we do want to give you an opportunity, if you've
24 traveled specifically because you wanted to make a
25 presentation. So you sign up for that outside the door at

1 the registration table. And we will come back to that
2 later.

3 Second, I just want to repeat that for those that
4 are interested in having information about the meeting in
5 California on July 20th, again it's a repeat meeting. We're
6 asking the same speakers not return and make the same
7 statements again, but the Federal Register notice does
8 provide a contact in California. Her name is Janet McDonal.
9 She's actually here--or was here a second ago--right up here
10 in the back. The Federal Register has her phone and FAX
11 number. In addition, her e-mail address--because the others
12 have been so difficult in getting through--is JMcDonal--it's
13 like JMcDonald without the D at the end. If you include the
14 "D" you're going to have trouble--@ORA.FDA.gov--and the ORA
15 is because our field offices are under the Office of
16 Regulatory Affairs at the FDA.

17 I also need to make an announcement for one person
18 that we're not sure we can find in the audience, from our
19 Chief Counsel's Office. Alexis Barnett, if you're here, you
20 have a conference call at 1:30.

21 [Laughter.]

22 Sorry to have an embarrassment if that occurred,
23 but I was handed a note, so I thought maybe I should read
24 it.

25 With that, let me welcome everybody to the

1 afternoon session. For those who were not here this
2 morning, we are engaging in a public dialogue on, really,
3 how to stake a step back, four years after DSHEA and say
4 "How are we going to develop a long-term blueprint to make
5 this law work and fully implement it?"

6 We've talked about a lot of issues so far. We
7 have divided the day up into several panels. There is an
8 agenda that is orange that all of you have out here, and I
9 think, without further ado, we will invite the next panel
10 up.

11 We have three people on this. The first is a
12 representative from the National Woman's Health Network,
13 Adrian Fugh-Berman. Second is Citizens for Health, James
14 Turner. And the third is Center for Science in the Public
15 Interest, Ilene Heller. If the three would please come up
16 and join us at the table, we will go through and ask each
17 speaker to make a five minute presentation in the order that
18 I've just described. It looks a little different when
19 you're up here, but we have a young lady sitting in the
20 front row who will give you a one-minute warning and a final
21 time. And we do ask you if would adhere to that. We had
22 terrific compliance this morning with that, and it's very
23 helpful in moving along.

24 We will then go through and each member of the FDA
25 panel will ask one question, and at the end of which I'll